MESH – FROM CONFUSION TO RESOLUTION

Addressing the Patient Needs

Professor Sohier Elneil

UCL Professor of Urogynaecology

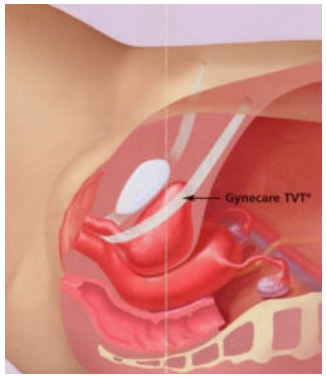
Faculty of Population Health Sciences

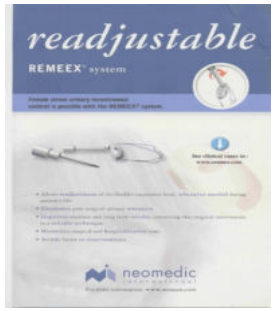
University College London

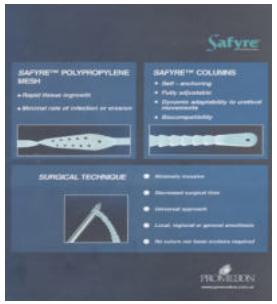
THE MESH JOURNEY

It is all about the History

Incontinence Mesh Types

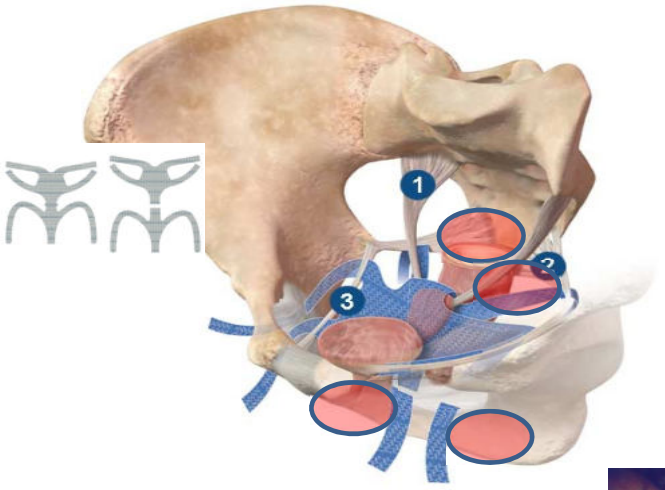




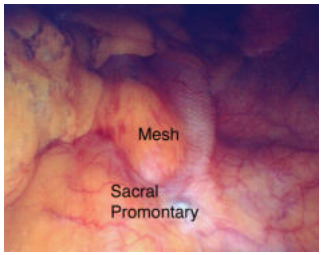


Prolapse Mesh Types

Vaginal



Abdominal/Laparoscopic



MESH IMPLANTATION SUMMARY

1997 Continence mesh Invented
2003 MHRA Approved and widespread use commences
2005 POP mesh widespread use
2017 Media Alert
2019 Mesh pause commences
2020 Cumberlege Report *'First Do No Harm'*
2021 Complex Mesh Centres open

SE MESH EXPLANTATION SUMMARY

1997 -
2003 -
2005 SE complex mesh removal surgery evolution begins
2007 Patient Focus Group 1
2016 Imaging development
2019 Restriction on practice/Professional societies restriction
2020 Win NHSE Bid for The London Complex Mesh Centre
2021 Complex Mesh Centres open

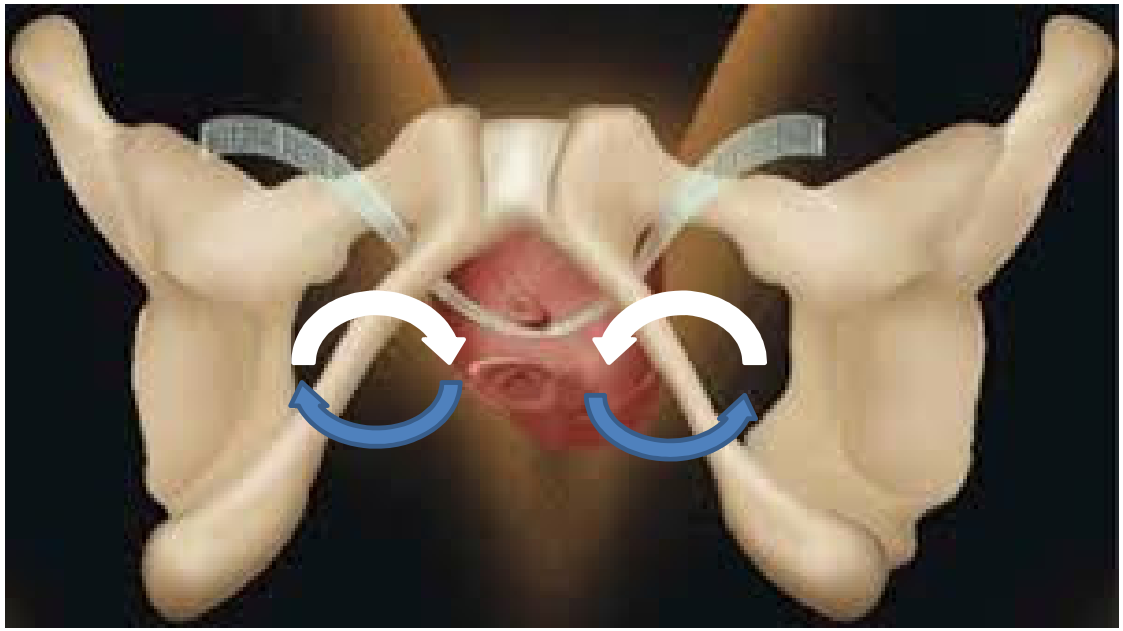
SE MESH REGULATORY WORK

1997 -
2003
2007 SE NICE IPAC Committee
2011 SE MHRA Continence Mesh Panel
2012 SE MHRA POP Panel leads to 2014 Safety Alert
2015 NHSE Mesh Committee Outcomes
2017 SE NICE IPAC committee Tenure Completed
2019 NHSE Complex Mesh Centre Committee

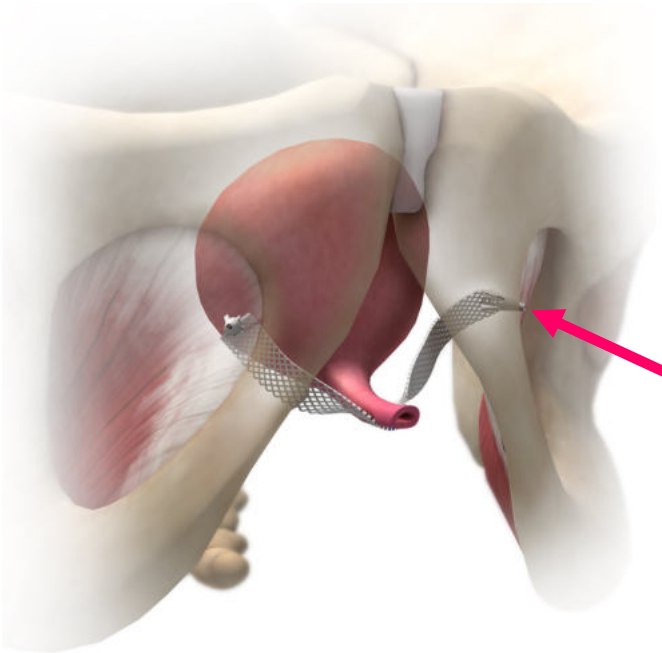
TRANSOBTURATOR CONTINENCE MESH

White mesh usually a TOT: uses <u>outside-in</u> technique

Blue mesh usually TVT-O: uses <u>inside-out</u> technique



MINI-SLINGS (OR SINGLE INCISION SLINGS)



Mesh inserted through a small incision in the anterior vaginal wall and secured onto the obturator fascia with a hook

No need to exit the skin in the groin area like TVT-O and TOT

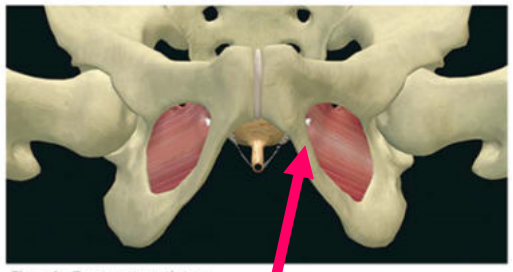
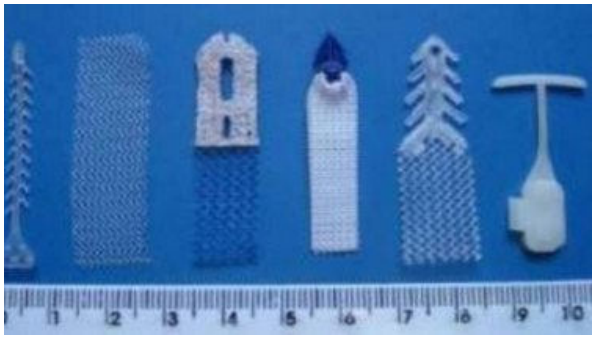
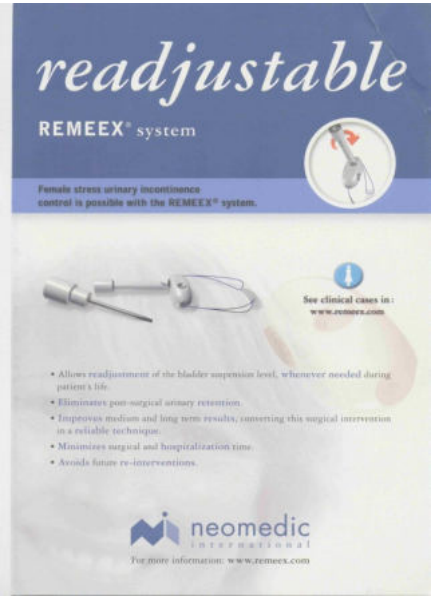


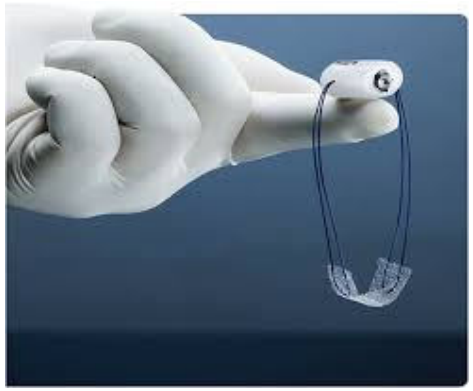
Figure 1 – Tape insertion technique.

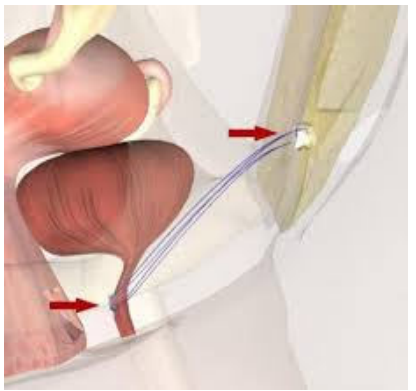


Different Obturator hooks

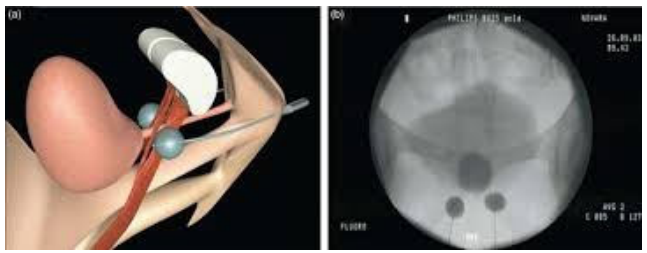


Mesh inserted through a small incision in the anterior vaginal wall and the strings/plastic device is secured onto abdominal fascia
The patient coughs, and the screw is tightened to tighten the strings attached to the mesh, thus putting pressure on the urethra. This continues until the patient stops losing urine via the urethra.





ADJUSTABLE CONTINENCE MESH DEVICES

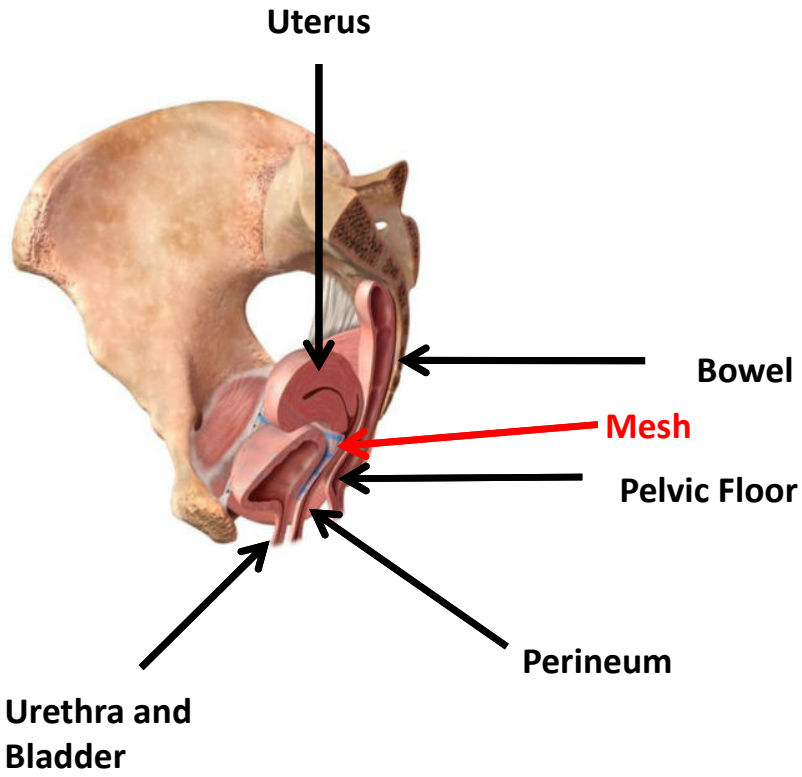


Mesh inserted through a small incision in the anterior vaginal wall and strings attached to the mesh are secured onto abdominal fascia with balloons situated on either side of the urethra

The patient coughs, and the balloons are filled with water to tighten the pressure on the urethra, until the patient stops losing urine via the urethra

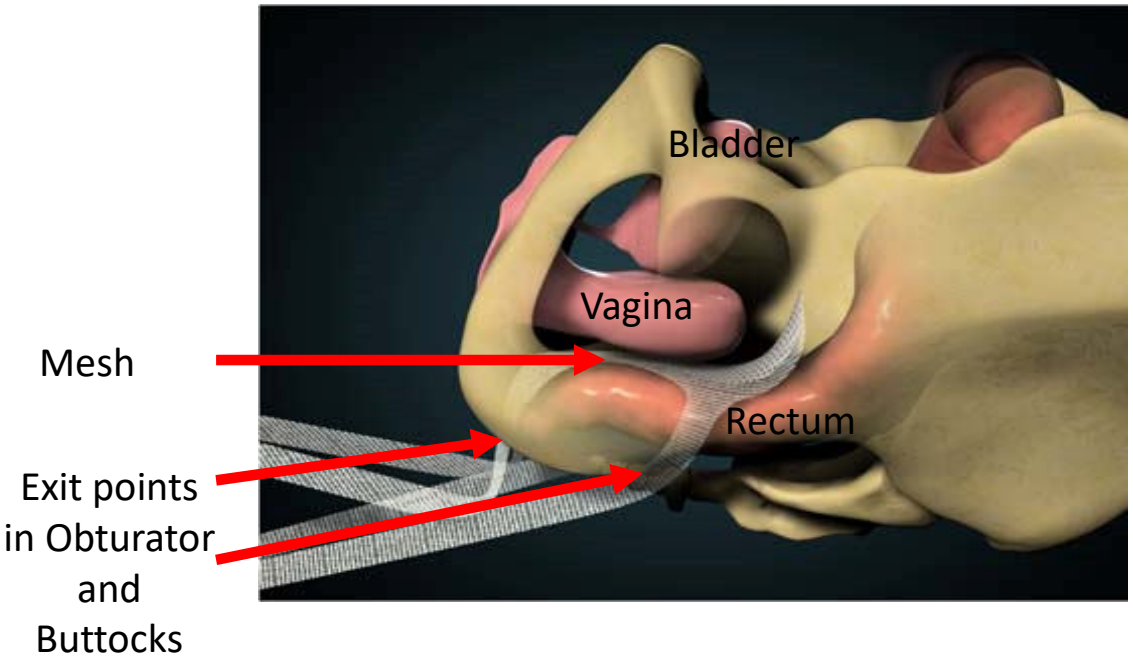
ANTERIOR VAGINAL WALL MESH

Bladder Prolapse (Cystocoele) Repair

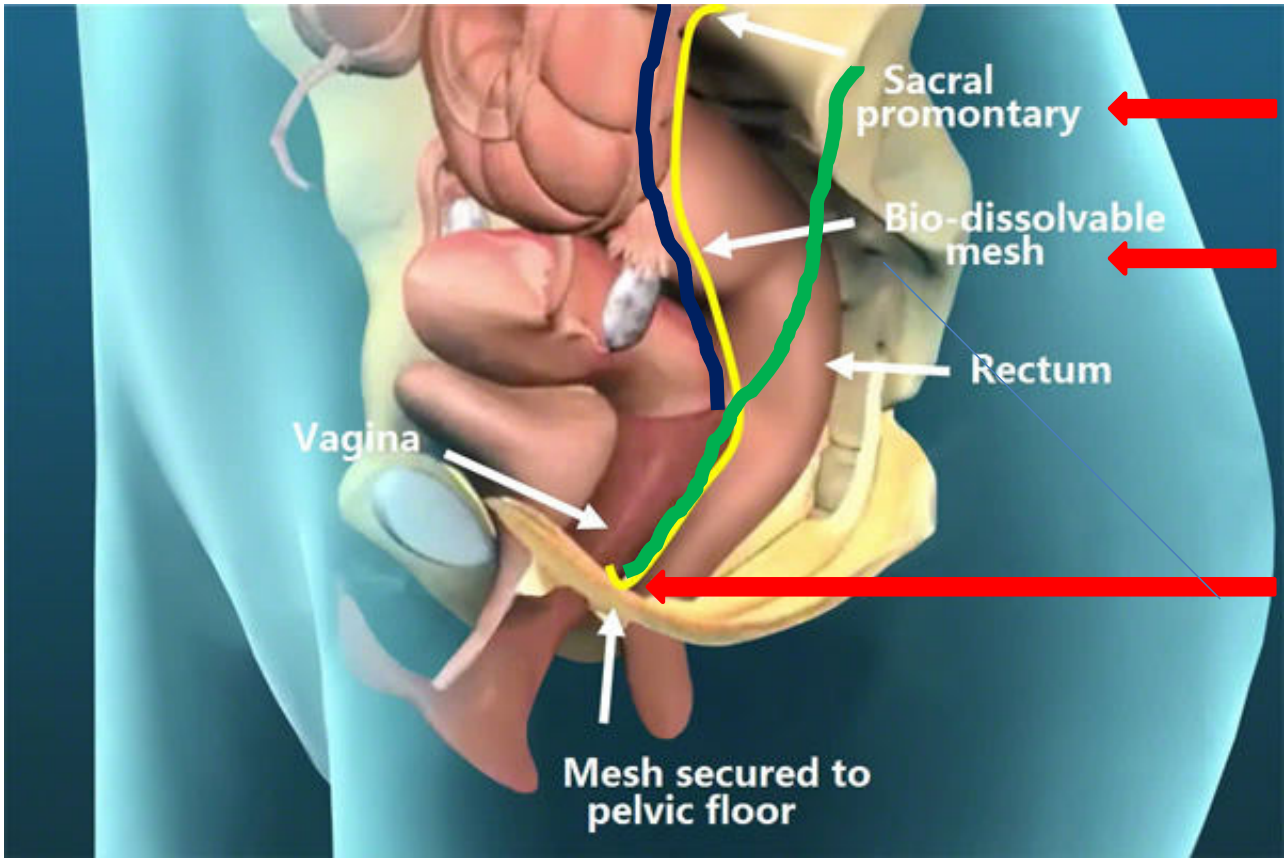


POSTERIOR VAGINAL WALL MESH

Posterior vaginal wall (Rectocoele)prolapse Repair

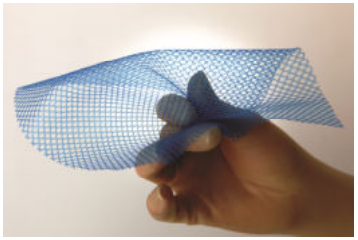


RECTOPEXY MESH



Protacks or Ethibond Sutures

Polypropylene Mesh



Ethibond/Vicryl/Prolene Sutures and Staples

HYSTEROPEXY MESH **SACROCOLPOPEXY MESH**

ABDOMINAL PROLAPSE MESH

How we used to work

How we work NOW

Listen to the Patient

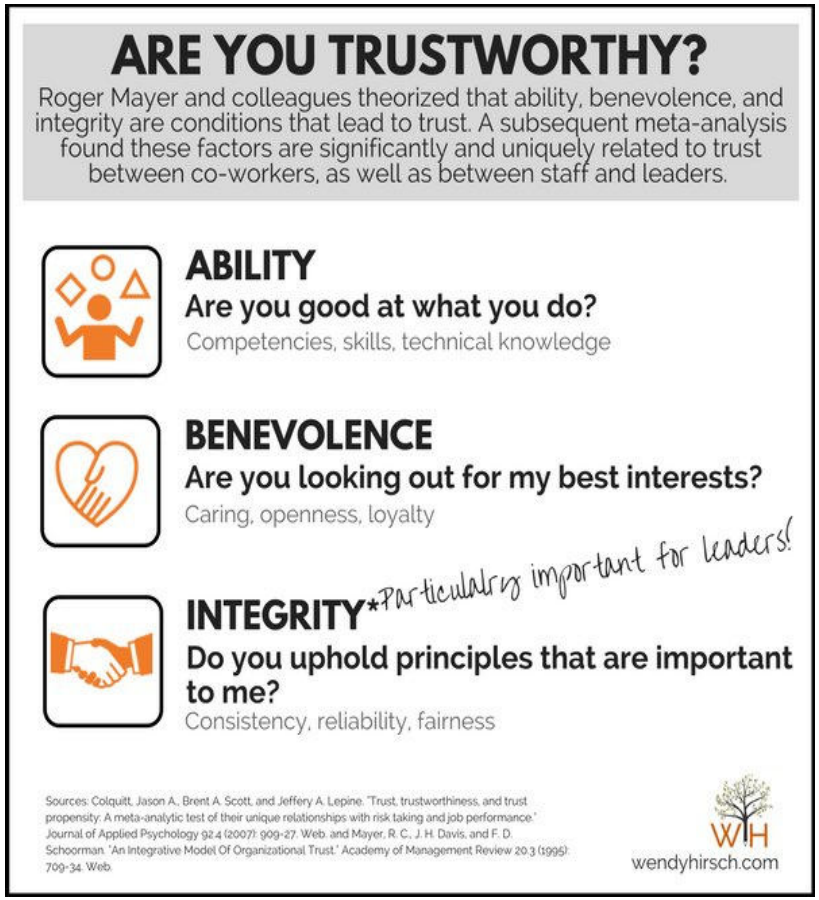
Interact with the Patient

Guidelines/Guidance Applied

It's a road map NOT a legal framework

Loss of Trust

We must listen to
What our patients say



MeshArtByBlair, 2017

THE POLITICAL LANDSCAPE SHIFT

UCL EGA Institute for Women's Health

2017 *Sling the Mesh* Campaign

Membership Total >10000

UK, Spain, Sweden, France, South Africa, Portugal, Dubai, Belgium

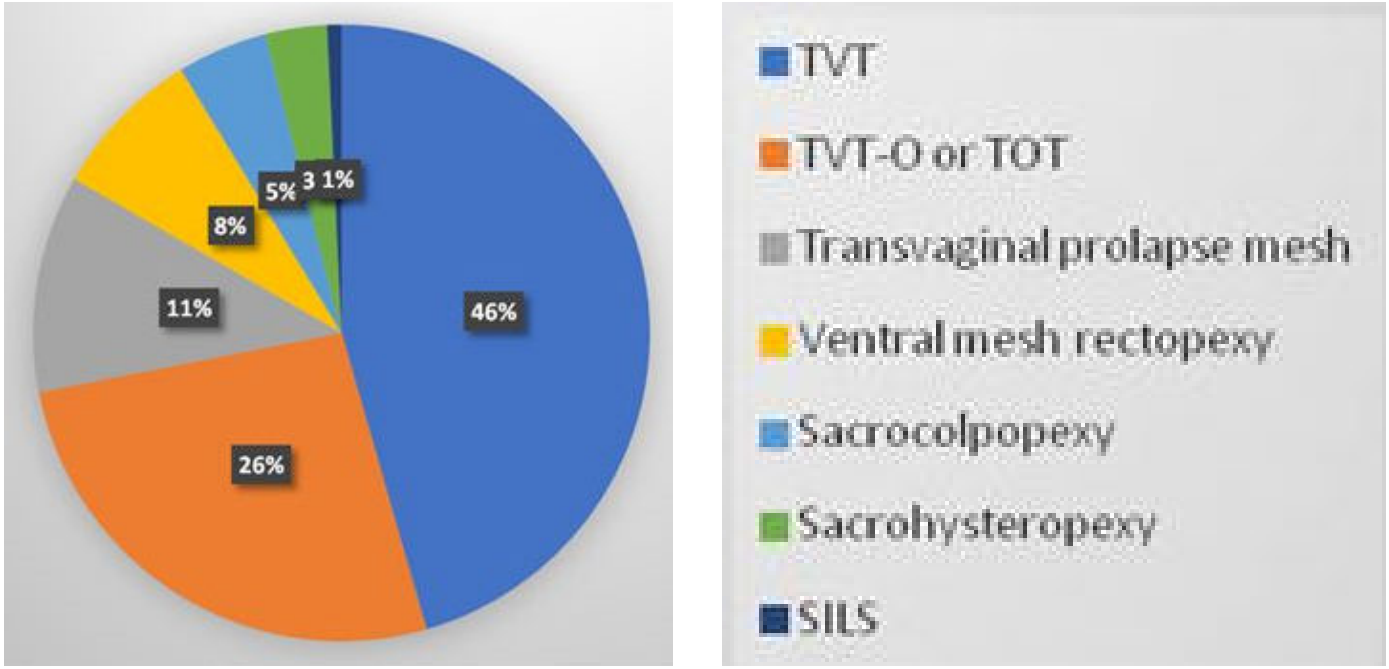
POLITICAL CAMPAIGN GROWS

- Oct 2017: Westminster Hall debate
- Nov 2017: All Party Parliamentary Mesh Group
- Jan 2018: Government announce review into three women's health disasters: Mesh, Sodium Valproate, and Primodos
- Feb 2018: House of Lords mesh question time on 100th anniversary of women's right to vote
- April 2018: House of Commons 3-hour debate
- July 2018: Mesh suspended awaiting outcome of safety review; outcome due April 2019
- Oct 2018: NICE publish new draft guidelines; similar to 2003
- Nov 2018: NHS prepares new guidelines for treatment

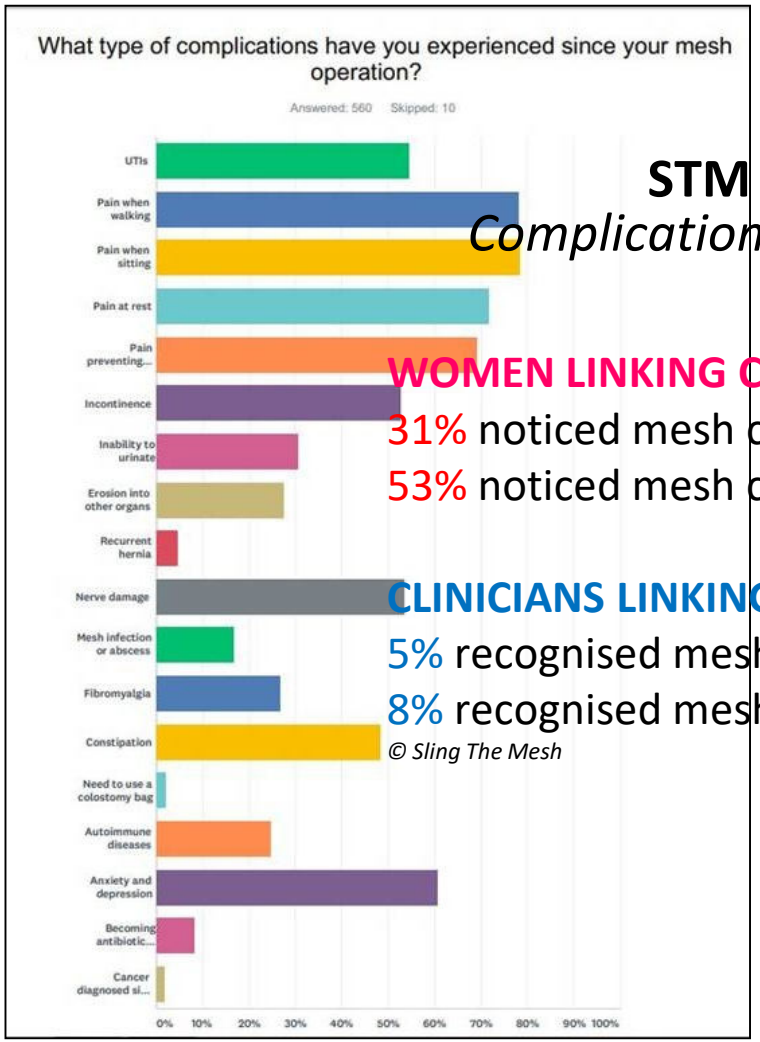
STM SURVEY 2018: MESH TYPES

Incontinence mesh 73%

Prolapse mesh 27%



STM SURVEY 2018: CLINICAL COMPLICATIONS (N=560)



STM SURVEY SEPTEMBER 2018

Complications are significantly under-diagnosed

WOMEN LINKING COMPLICATIONS

31% noticed mesh complications within 3 months of surgery

53% noticed mesh complications within 6 months of surgery

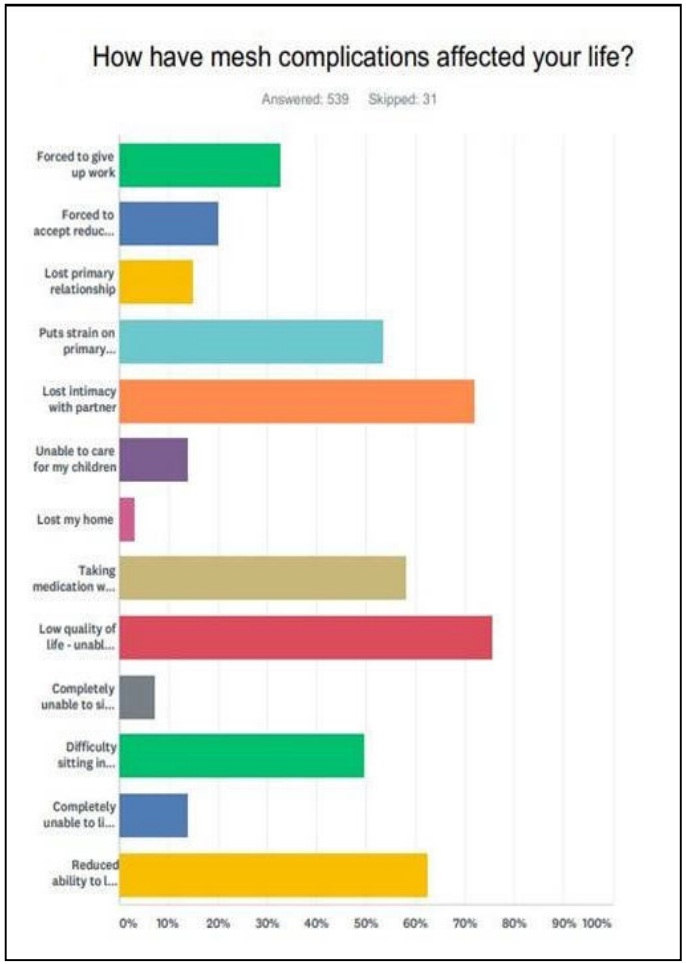
CLINICIANS LINKING COMPLICATIONS

5% recognised mesh complications within 3 months of surgery

8% recognised mesh complications within 6 months of surgery

- Pain affects daily life 78%
- Loss of sex life 70%
- Anxiety and depression 60%
- UTIs 54%
- Nerve damage 53%
- Incontinence 52%
- Constipation 48%
- Inability to urinate 30%
- Erosion into other organs 27%
- Fibromyalgia 26%
- Need a colostomy bag 2%

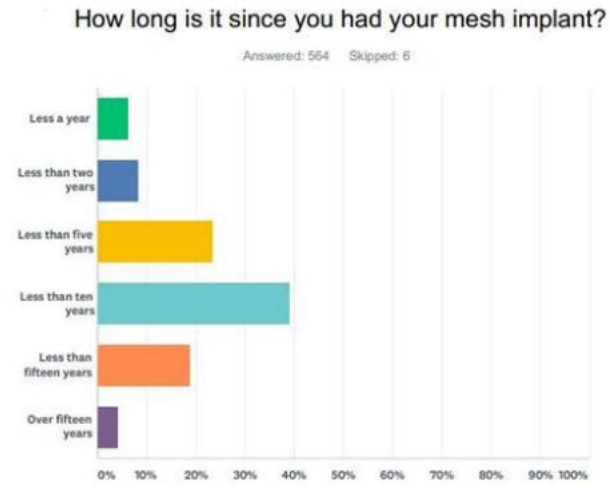
STM SURVEY 2018: ‘SHATTERED LIVES’ (N=539)



- Can’t enjoy socialising/hobbies 75%
- Reduced ability to lift shopping, cook, or clean 62%
- Medication side effects 58%
- Strain on primary relationship 53%
- Difficulty sitting in vehicles or on public transport 49%
- Forced to give up work 32%
- Reduced working hours 20%
- Lost marriage 15%
- Unable to care for children 13%
- Lost home 3%

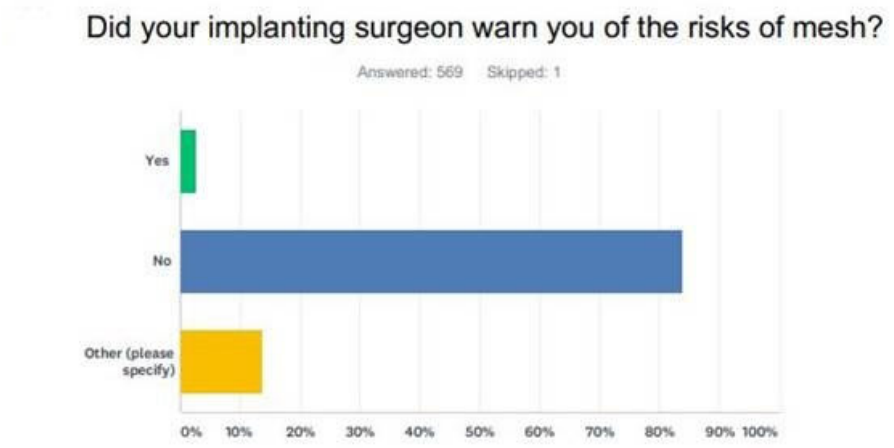
STM SURVEY 2018: HOW LONG HAVE WOMEN SUFFERED (N=564)

- < 1 year 6%
- 2 to 5 years 23%
- 5 to 10 years 40%
- > 15 years 5%



ANSWER CHOICES	RESPONSES	
Less a year	6.21%	35
Less than two years	8.16%	46
Less than five years	23.40%	132
Less than ten years	39.18%	221
Less than fifteen years	18.79%	106
Over fifteen years	4.26%	24
TOTAL		564

STM SURVEY 2018: WHERE WE WARNED ABOUT COMPLICATIONS? (N=569)



ANSWER CHOICES	RESPONSES	
Yes	2.64%	15
No	83.83%	477
Other (please specify)	13.53%	77
TOTAL		569

- Yes 2%
- No 83%
- “Some risk” 13%

MY VOICE: DEVELOPMENT OF PIL

PATIENT FOCUS GROUP

- **10 women affected by mesh**
- **Reviewed current pathways of care**
- **Reviewed access to care**
- **Prepared patient information leaflet**

E-mail review pf PIL with pain medicine fellow, urogynaecology fellows and colo-rectal fellow

Survey completed

Elneil and Team 2012

LITERATURE

Mesh Removal Surgery

Outcome of Transvaginal Mesh and Tape Removed for Pain Only

Hou JC, Alhalabi F, Lemack GE, Zimmern PE

J Urol 2014;192:856–60

Treatment and outcome of polypropylene mesh or tape related pain after reconstructive pelvic surgery [Article in Chinese]

Wang YQ , Yang X, Wang JL.

Zhonghua Fu Chan Ke Za Zhi. 2016 Dec 25;51(12):901-908. doi: 10.3760/cma.j.issn.0529-567X.2016.12.005.

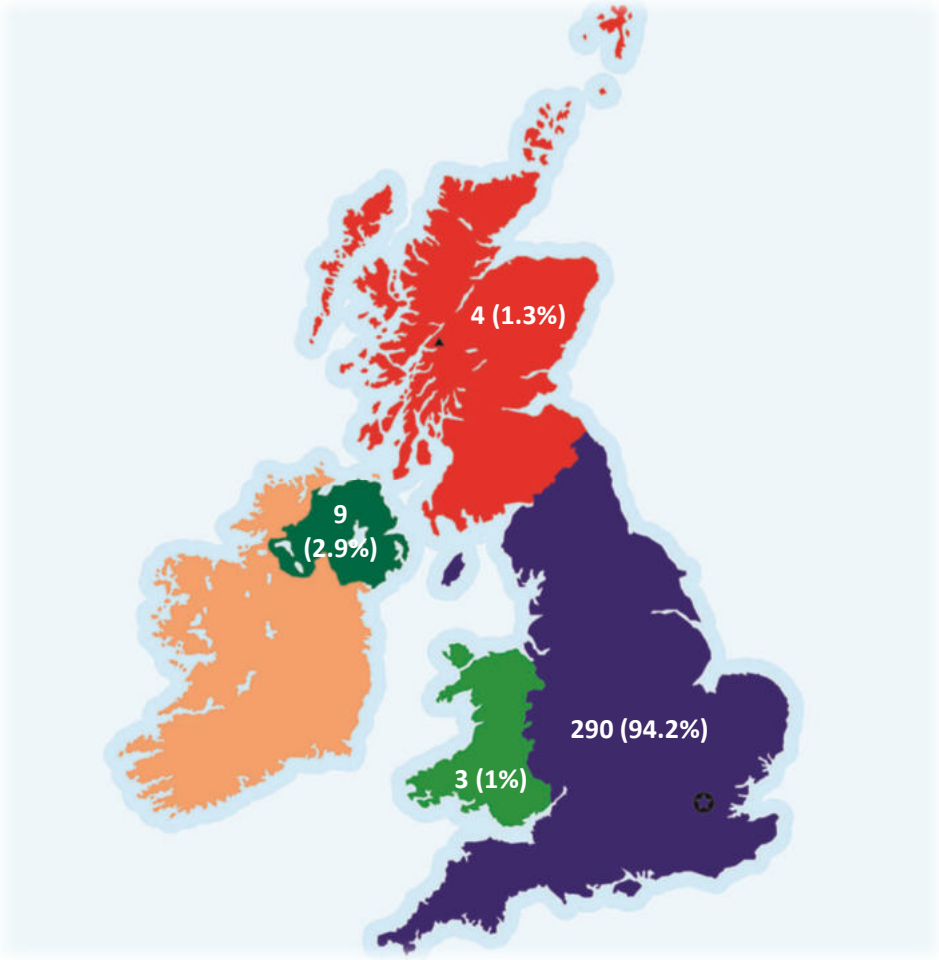
Autoimmune Impact

Host response to synthetic mesh in women with mesh complications

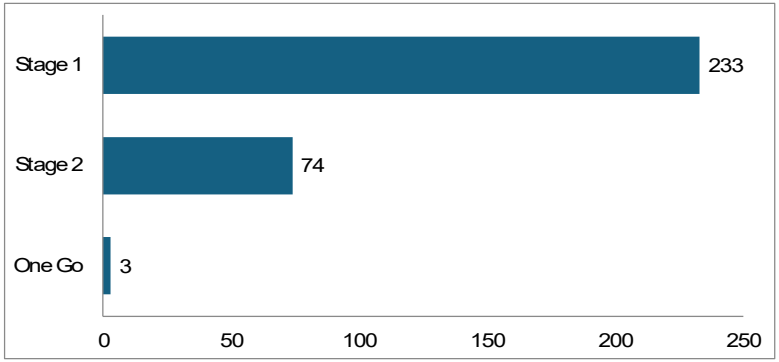
Alexis L. Nolfi, BS; Bryan N. Brown, PhD; Rui Liang, MD; Stacy L. Palcsey, BS;

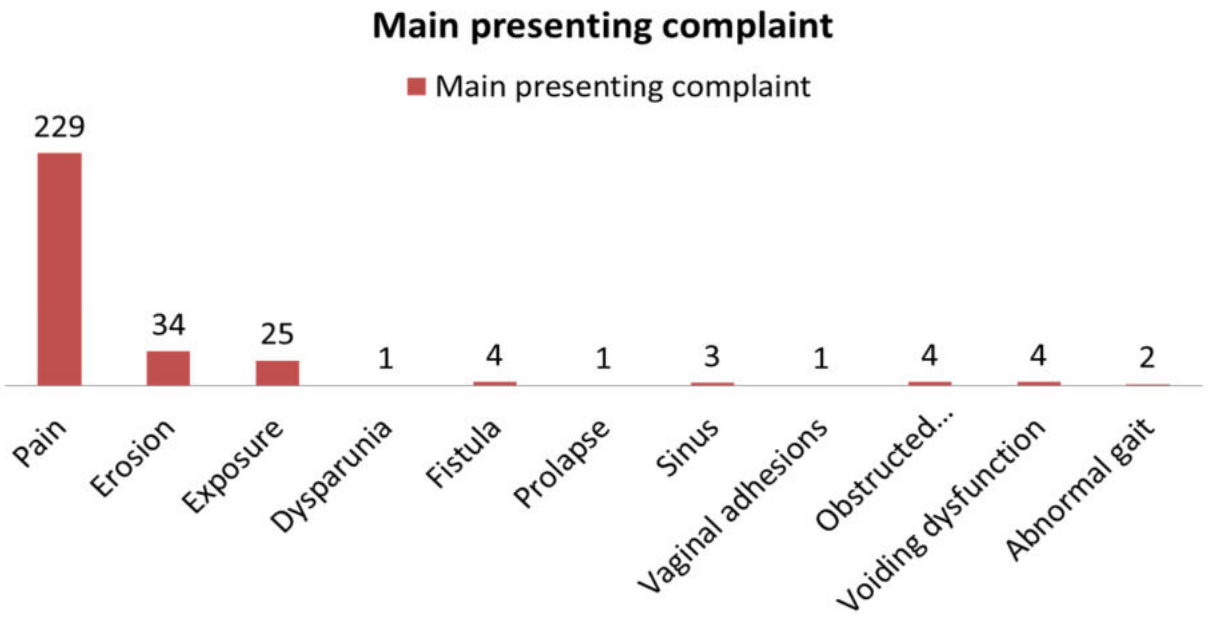
Michael J. Bonidie, MD; Steven D. Abramowitch, PhD; Pamela A. Moalli, MD, PhD

Geographic location: Referred Patients 2015-2020

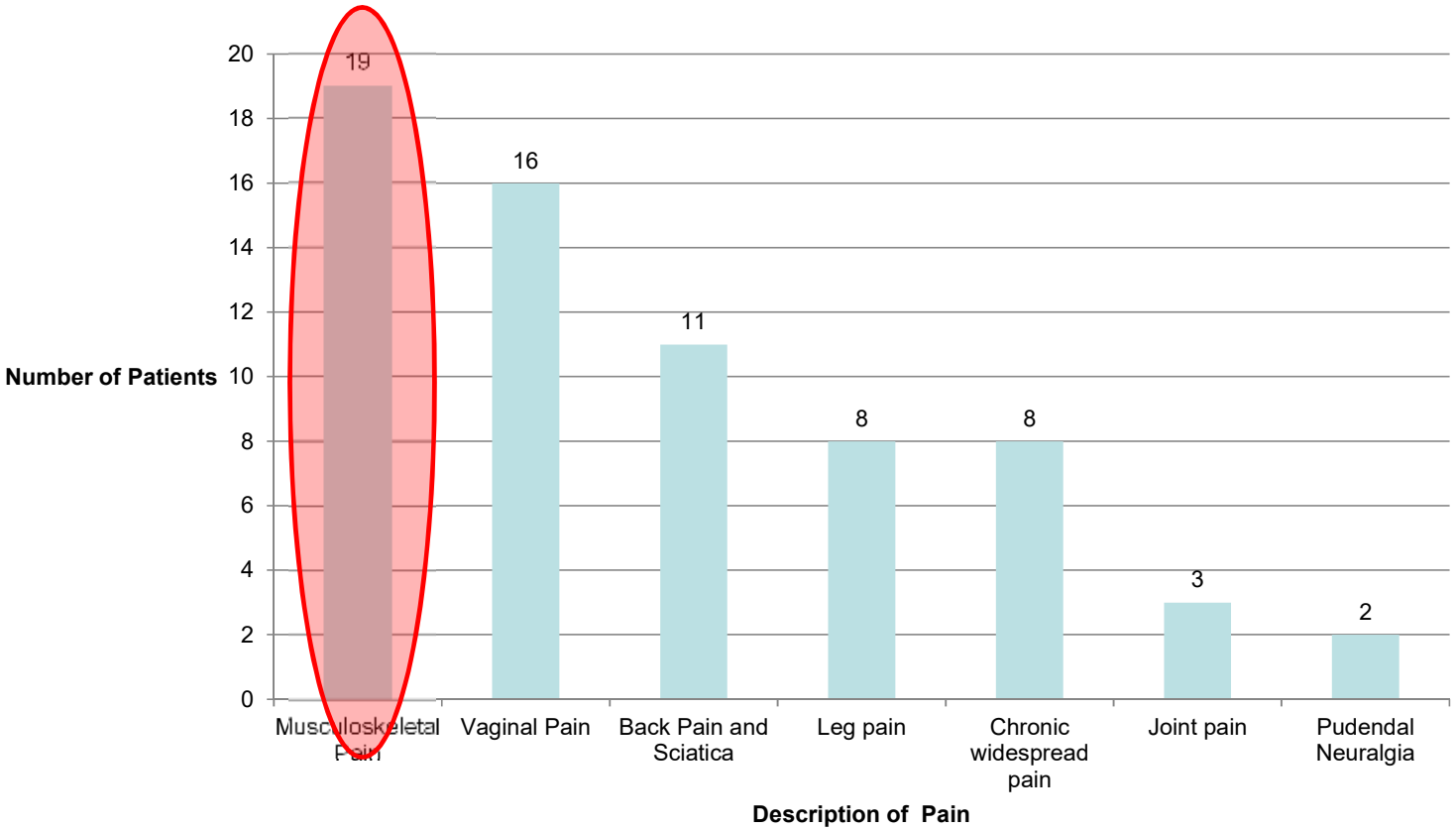


Mesh Removal 2015-2020



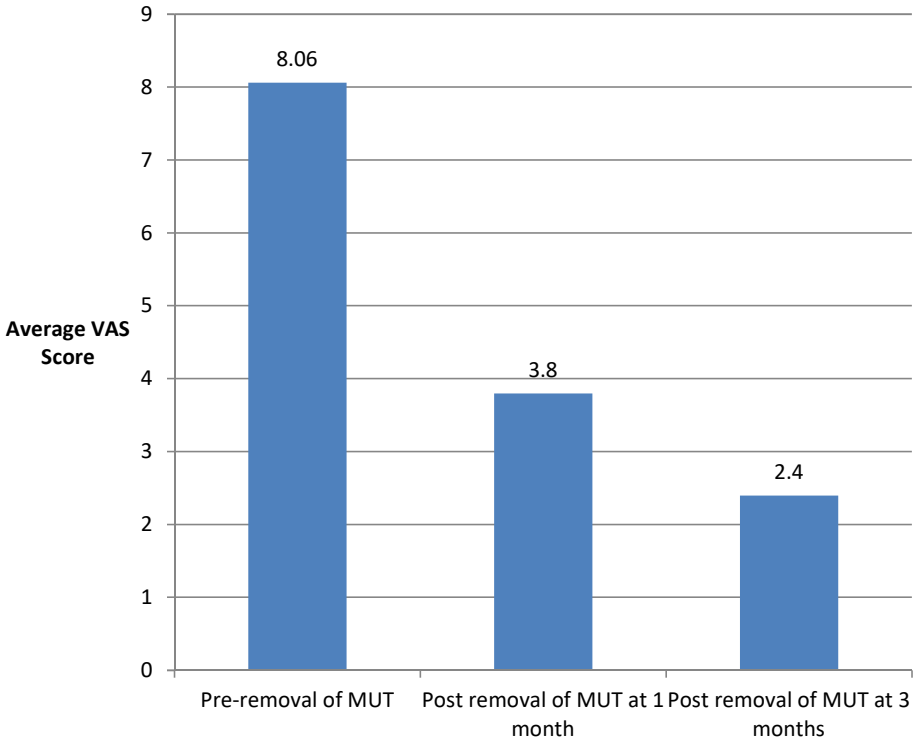


Pain symptoms seen in patients presenting with chronic pelvic pain following mid-urethral tape insertion



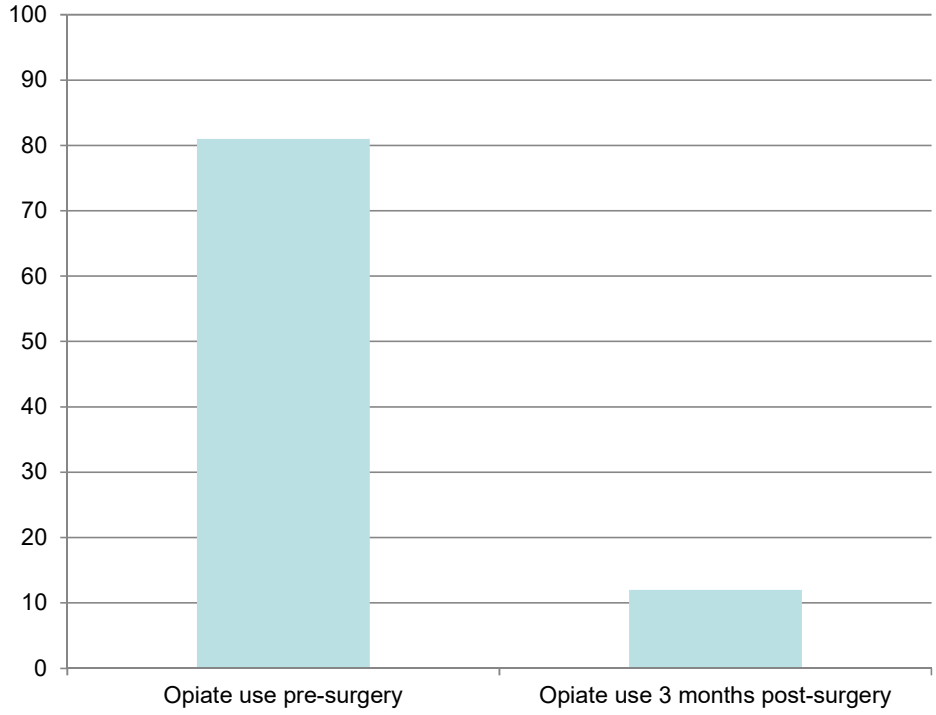
Pain VAS Scores

Pre- and Post- Removal of Mesh



Opiate use

Pre- and Post- Removal of Mesh

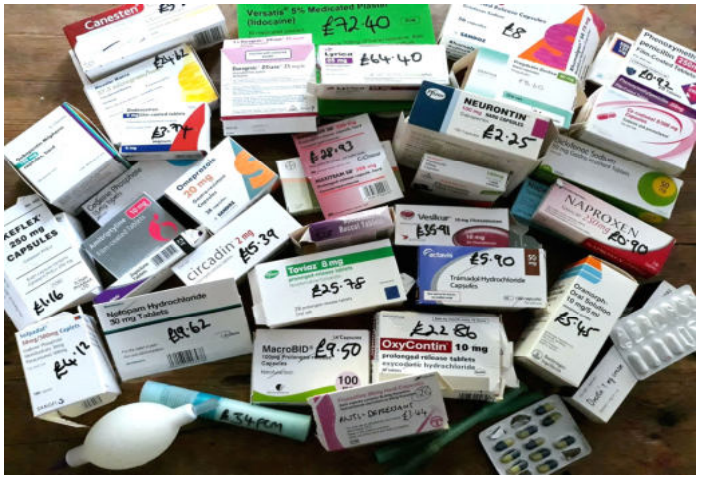


Elneil, 2014

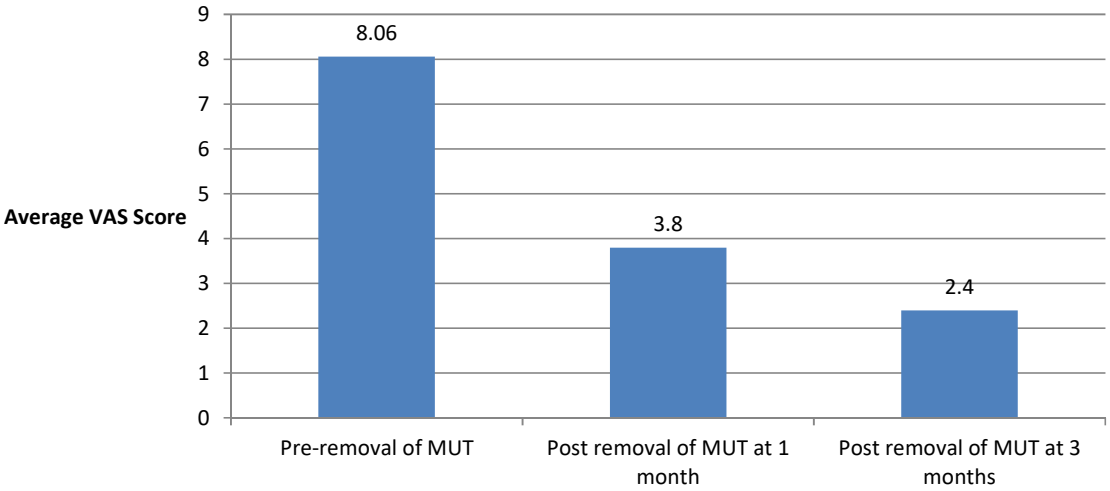
European Association of Urology

Guidelines on Chronic Pelvic Pain

D. Engeler (chairman), A.P. Baranowski, S. Elneil, J. Hughes,
E.J. Messelink, P. Oliveira, A. van Ophoven, A.C. de C. Williams



Pain VAS Scores
Pre- and Post- Removal of Continence Mesh



Mesh-Associated Pain Syndrome: Predictors for Continence and Prolapse Mesh Removal Surgery in a Single Centre

Journal:	*BMJ*
Manuscript ID	Draft
Article Type:	Original research
Date Submitted by the Author:	n/a
Complete List of Authors:	Elneil, Sohier; University College London; University College London Hospitals NHS Foundation Trust De Lanerolle, Gayathri; University of Oxford Medical Sciences Division, Department of Psychiatry Zeng, Yutian; Southern University of Science and Technology Chunli, Deng; Southern University of Science and Technology Shetty, Ashish; University College London; University College London Hospitals NHS Foundation Trust Shi, Jian Qing; Southern University of Science and Technology; Alan Turing Institute
Keywords:	Urinary incontinence, General surgery

HOW DID WE CHANGE COURSE?

MHRA WORKSHOP ON VAGINAL TAPES FOR STRESS INCONTINENCE
Wednesday, 6 March 2011
10:00-16:00
Room RT 410

MHRA WORKSHOP ON VAGINAL MESHES FOR PELVIC ORGAN PROLAPSE
Wednesday, 28 March 2012
10:00-16:00

151 Buckingham Palace Road, London, SW1W 9SZ

CHAIR: PROFESSOR PAUL ABRAMS

NICE/IPAC Representative S Elneil

PERCEPTION: REGULATORS FAIL WOMEN

2012

MHRA commissions the York Report

- Appears to cherry pick studies and quotes 1-3% risk
- It omits loss of sex life risk 14.5%

Regulators say benefits outweigh risks of harms

- MHRA quotes this report for the next 5 years

MHRA meeting indicates CE mark may be an issue for mesh products

MHRA Committee onf the Safety of Devices 2012

If a device is causing havoc but functioning normally, it can only be removed from the market if the device itself is not performing properly or was unsafe

2014

MHRA issues a patient safety alert

MHRA/NICE/NHS ENGLAND MESH COMMITTEE

March 2012-2015

Main Recommendations

- **Listening to the patient**
- Patient Selection and Training
- More human trials
- PIL in Detail
- RCOG and RCS Centres of excellence via BSUG, BAUS incorporating mesh removal expertise, UG, Colo-rectal, Urologist, Pain Mx
- **Clinical quality, Data, Consent**

Complications following vaginal mesh procedures for stress urinary incontinence: an 8 year study of 92,246 women

- Kim Keltie, Sohier Elneil, Ashwani Monga, Hannah Patrick,
- John Powell, Bruce Campbell & Andrew J. Sims

Table 2

The total number of patients (%, percentage of cohort) who had a trans-vaginal tape (TVT), transobturator tape (TOT) or suprapubic sling (SS) mesh insertion (in the absence of concomitant procedures) who were re-admitted during the study period for further mesh surgery or due to complications from previous mesh surgery. Results are uncorrected for censoring.

For example, 2248 of 41,880 (5.4%) patients who had a TVT mesh inserted were re-admitted at least once during the period of follow-up (mean follow-up of 4.2 years).

9.8%

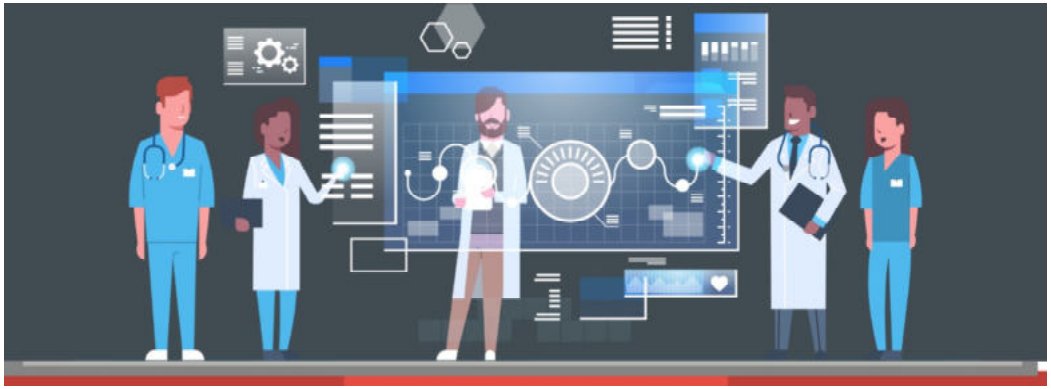
Procedure type	Number of readmissions				Maximum number of readmissions
	0	1	2	3+	
TVT	39,632 (94.6)	1737 (4.1)	375 (0.9)	136 (0.3)	6
TOT	24,254 (95.1)	1017 (4.0)	174 (0.7)	64 (0.3)	6
SS	574 (93.6)	34 (5.5)	4 (0.7)	1 (0.2)	3
All (combined)	64,460 (94.8)	2788 (4.1)	553 (0.8)	201 (0.3)	6

MESH COMPLICATIONS RECOMMENDATIONS

What's missing

1. Class III invasive devices require data from a clinical trial in accordance with the clinical trials regulation
2. Publicly accessible registry of licensed invasive devices with details of marketing status and linked equivalence evidence
3. Devices withdrawn for potential safety concerns should make all approval evidence and postmarketing data publicly available.
4. Registry of who pays whom – Sunshine Act

ICD11: MESH



Parent

PK96 Obstetric or gynaecological devices, implants or grafts associated with injury or harm

23 External causes of morbidity or mortality

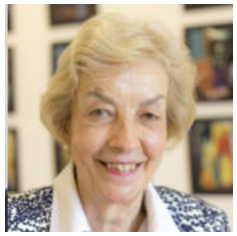
Causes of healthcare related harm or injury

Surgical or other medical devices, implants or grafts associated with injury or harm in therapeutic use

PK96 Obstetric or gynaecological devices, implants or grafts associated with injury or harm

PK96.2 Obstetric or gynaecological devices associated with injury or harm, prosthetic or other implants, materials or accessory devices

The Independent MEDICINES & MEDICAL DEVICES Safety Review



Baroness Cumberlege CBE DL

The Review was announced in **February 2018** by the Secretary of State for Health and Social Care, the Rt Hon Jeremy Hunt MP, in the House of Commons. He stated that it would examine how the healthcare system has responded to concerns raised by patients and families about three medical interventions:

- the hormone pregnancy test Primodos
- the anti-epileptic drug sodium valproate
- **surgical mesh**

The Secretary of State said that the **system's response to these concerns was "not good enough".** He announced that the Review, to be chaired by Baroness Julia Cumberlege, would consider a range of matters, including:

- whether any further action is needed relating to the complaints around Primodos, sodium valproate and surgical mesh
- the processes followed by the NHS and its regulators when patients report a problem
- how to make sure communication between the different groups involved is good

The Review may make recommendations regarding the three specific interventions but also about how the healthcare system can improve its response to concerns raised about other medicines and medical devices in the future.

June 2018

UCL EGA Institute for Women's Health

The Cumberlege Review 2020

First Do No Harm

The report of the Independent Medicines and Medical Devices Safety Review

Chapter 5: Mesh	
Further research is urgently needed so that a clearer view can be reached on the inherent properties and safety of pelvic mesh.	5.33
Medical device manufacturers must research and develop a remedial strategy to address any severe complications caused by their product. This strategy should be set out in the Instructions for Use (IFUs) and guidance. The strategy should be developed collaboratively with appropriate input from others, such as the regulators and the commissioners of any services required to carry out actions.	5.38
We recommend that when a device or procedure is introduced a cohort of early recipients undergo enhanced reporting to detect unexpected adverse impacts.	5.52
NICE's most recent guidance states that the Transvaginal Tension Free Vaginal Tape-Obturator (TVT-O) should not be offered routinely. In the future, we feel the TVT-O should only be used in exceptional circumstances, if at all.	5.55
Professional bodies should lead on ensuring surgeons only operate within their capabilities. They must provide guidance for their members and ensure that surgeons are appropriately trained, and this should be assured through the appraisal process.	5.56
A culture must exist where all multi-disciplinary team (MDT) members feel able to speak up and that their input will be listened to. Trusts must work to create a culture that facilitates effective MDTs.	5.58

9 RECOMMENDATIONS

Conservative measures must be offered to women before surgery. We have heard that specialist pelvic floor physiotherapy cannot match the current demand. The service commissioner should identify gaps in the workforce and notify specialist clinicians, professional organisations and Royal Colleges. A co-ordinated strategy can then be developed to remedy the gap.	5.59
Clinicians must ensure patients have sufficient understanding of their treatment including the benefits, the potential risks it presents, and the alternative treatment options, including doing nothing, in order to decide whether they are willing to have that treatment.	5.60
Clinicians need to establish and agree terminology and definitions related to both mesh insertions and removals.	5.68
An audit to establish complication rates should be attempted using the women who had mesh insertions in 2010.	5.87
A consensus needs to be reached on whether it is better to carry out full or partial removals. This is a clinical matter, and it must be done collaboratively, including consulting international experts. This consensus should be validated by carrying out follow up on those who have removals at the specialist centres. We strongly recommend that NICE actively monitor the situation and update their guidance promptly once a consensus has been reached.	5.95
Consideration should be given to credentialing a small number of centres and surgeons for particular complex pelvic mesh surgeries.	5.102
A remote counselling service along the lines we set up during this Review should continue to exist.	5.105
Pelvic floor education should be encouraged, where appropriate, in schools and certainly in antenatal classes. In addition, we recommend that the NHS adopts the French model for universal post-natal pelvic floor rehabilitation.	5.123
Dismissive, defensive attitudes by surgeons are a cultural issue that needs to be addressed by the medical profession, its professional bodies and regulators.	5.124

UCLH Board Visit October 2022

'Amazing work at UCLH implementing my recommendations'

MOVING FORWARD

THREE AREAS OF FOCUS

Working Group recognised a need to focus on three broad areas which encompass the identified issues. These are

- **Clinical Quality**
- **Data and Information**
- **Informed Consent**

ORIGINAL LONDON COMPLEX MESH MDT SERVICE

Team Leads

Sohier Elneil - Clinical Lead (Urogynaecologist)
Tamsin Greenwell - Deputy Clinical Lead (Urologist)
Austin Obichere - Lead for Colo-rectal Surgery
Andrew Baranowski - Lead for Pain
Paul Aughwane – Lead Imaging Radiology
Ghada Salman – Lead Imaging Gynaecology
Jacqueline Doyle - Lead for Clinical Psychology
Esther Kuria - Creator of the LCMC Nursing Pathway and LCMC ERP
Elspeth Rai - Lead for Physiotherapy
Julia Cambitzi - Lead for Pain Nursing

Other Team Members

Team Urogynaecology - Anni Baha Khan
Team Urology - Jeremy Ockrim, Helena Gresty
Team Pain - Moein Tavvakoli, Victoria Tidman, Katrine Petersen
Team Psychology - Jacqueline Hughes, Philomena Da Silva
Clinical Fellows - Stefania Palmeri, Nihal Mohammed
Team Nursing - Jigna Shah, Niqueala Anderson, Claire Nicholls,

Managerial and Admin Team:

Tim Hodgson - Medical Director, Specialist Hospitals Board
Stuart Lavery- Divisional Clinical Director
Nicola Winn - Divisional Manager
Service Lead - Helen Light
MDT Coordinator - Raymond Sarfoh
Team Admin - Eva Verbatchi

Referral information

We are now accepting GP and tertiary referrals to the London Complex Mesh Centre. To make a referral, please download and complete the form 'LCMC referral form', and send to uclh.referrals.uclh_lcmc@nhs.net.

Please refer to the MRI protocol documents (sacrocolpopexy, sacrohysteropexy or rectopexy mesh and TVT, TOT and urethral mesh) to support local imaging for mesh ahead of sending patient referrals.

If you have any questions about submitting a referral ahead of sending the referral form, please email uclh.enquiries.uclh_lcmc@nhs.net

https://www.uclh.nhs.uk/our-services/find-service/womens-health-1/gynaecology/london-complex-mesh-centre

London Complex Mesh Centre (LCMC) Overview

NHS
University College London Hospitals
NHS Foundation Trust

Context

- NHSE has established 9 regional specialist mesh centres in response to the mesh scandal and the Independent Medicines and Medical Devices report chaired by Baroness Cumberlege (July 2020).
- UCLH is the specialist centre for London and the South East so will receive referrals from across this patch (estimate ~ 200/year)
- The service has been set up as the London Complex Mesh Centre which will be primarily removing mesh (in circa 80% of cases)

The 9 regional mesh centres are:

1. Newcastle Hospitals NHS FT
2. Sheffield Teaching Hospitals NHS FT
3. Manchester University NHS FT
4. Cambridge University Hospital NHS FT
5. University College London Hospital
6. University Hospital of Leicester
7. Nottingham University Hospitals
8. University of Southampton Hospital
9. University Hospitals Bristol

ELNEIL TIER SYSTEM

A PROPOSED TIER SYSTEM FOR MESH COMPLICATION CENTRES

MESH	CONTINENCE MESH			VAGINAL PROLAPSE MESH		ABDOMINAL PROLAPSE MESH		
TYPE OF MESH	RETROPUBIC MESH	TRANS-OBTURATOR MESH	TRANS-OBTURATOR MESH REMOVAL	ANTERIOR VAGINAL WALL PROLAPSE MESH	POSTERIOR VAGINAL WALL PROLAPSE MESH	SACRO-HYSTEROPEXY OR SACRO-COLPOPEXY MESH	SACRO-HYSTEROPEXY OR SACRO-COLPOPEXY MESH	*RECTOPEXY MESH REMOVAL*
SURGICAL DESCRIPTION	Removal of vaginal and/or abdominal and/or vulval mesh (staged or one procedure)	Removal of vaginal mesh component only	Removal of vaginal mesh with obturator/groin or paralabial dissection	Removal of vaginal mesh with/without obturator dissection	Removal of vaginal mesh and sacro-spinous regional dissection	Division and removal of central component of mesh only	Division and removal of mesh with sacral dissection and uterine/cervical/ vaginal dissection	*Removal of mesh with Anterior resection, reanastomosis +/- temporary ileostomy*
TIER 1								
TIER 2								
TIER 3								
TIER 4								
TIER 5								

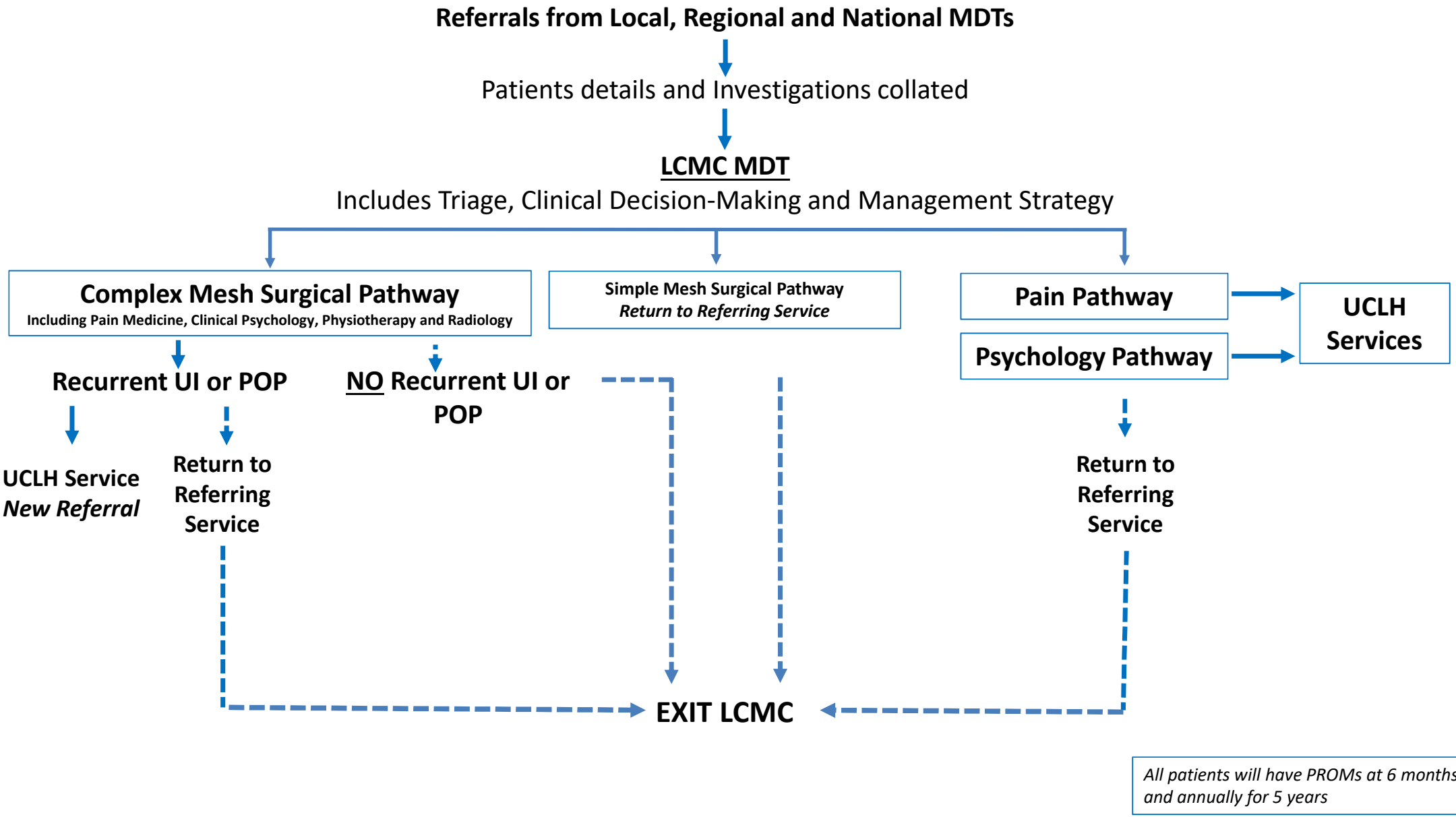
NB: Movement between Tiers is possible, dependent on the skill set available.

Elneil Proposal: Mesh Complication Centres Tier System and Surgical Definition/Terminology for Mesh Removal v.3 09/01/2020

Currently UCLH only Tier 5 Complex Mesh Centre in UK

LCMC MDT Patient Pathway Walkthrough

Created, Reviewed and Refined by Elneil, Patient Focus Group, and Members of the Wider MDT


Referrals from Local, Regional and National MDTs
Patients details and Investigations collated
LCMC MDT
Includes Triage, Clinical Decision-Making and Management Strategy
Complex Mesh Surgical Pathway
Including Pain Medicine, Clinical Psychology, Physiotherapy and Radiology
Simple Mesh Surgical Pathway
Return to Referring Service
Pain Pathway
Psychology Pathway
UCLH Services
Recurrent UI or POP
NO Recurrent UI or POP
UCLH Service
New Referral
Return to Referring Service
Return to Referring Service
EXIT LCMC
All patients will have PROMs at 6 months and annually for 5 years

LCMC

Weekly Meetings

Monday: LCMC MDT

TIME	NAME OF EVENT	DESCRIPTION OF EVENT
0815-0900	LCMC Steering Group Business meeting (UCLH Lead, Vice-Lead, COO, DCD, Programme Manager)	To review and act upon functioning of the MDT, guidelines, audits, improvement projects and patient survey.
0900-100	Triage MDT	To review all new patient referrals to the LCMC and check they fit eligibility criteria.
1000-1100	Clinical Decision-Making MDT 1	To review clinical history of patient and make decisions regarding pathway of care.
1100-1200	Clinical Decision-Making MDT 2	To review clinical history of patient and make decisions regarding pathway of care following mesh removal (treatment of incontinence and prolapse)
1200-1230	Clinical Decision-Making MDT 1 and 2 (UCLH with Colorectal Team)	To review clinical history of patient and make decisions regarding pathway of care.
1230-1300	MDT review of Long-Term Outcomes and PROMS (UCLH MDT)	To review long-term outcomes and PROMS (July 2022 onwards)

Ad Hoc Separate Meetings: Pain, Radiology, Nursing, Administration

Patient Walkthrough

CONTINENCE AND VAGINAL PROLAPSE MESH MDT PATHWAY

TRIAGE MDT

MONTH 0

POST TRIAGE MDT
Appointment 1: CNS Phone Review

OPD 1: Clinical Assessment (3 APPOINTMENTS)
Appointment 2: Surgical Team (F2F)
Appointment 3: Chronic Pain Team (F2F)
Appointment 4: Psychology (F2F)

CLINICAL DECISION MAKING MDT 1

UCLH Chronic Pain Management
UCLH Psychology Management

POST CLINICAL DECISION MAKING MDT
Appointment 5: CNS Phone review

EDUCATIONAL ONLINE SCHOOLS

ONGOING CARE
Appointment 6, 7, 8, 9, 10,11: CNS Key Worker Phone Review (Reviews every 8 weeks)
Appointment 12, 13, 14: Psychology F2F Reviews (every 12 weeks)

MONTH 3

SURGERY 1: Mesh Removal

Pre-SURGERY 1
Surgical Team Consent:
Appointment 15: F2F Consent
Appointment 16: Phone Consent Confirmation 4 weeks later
UCLH Pre-Assessment Anaesthetic Review
Appointment 17: F2F Review
Acute Pain CNS Review
Appointment 18: Phone Review

POST-OP OPD FOLLOW UP
Appointment 19 and 20:
Week 1 (if catheterised) and 4 (non-catheterised): CNS Review (Telephone)
Appointment 21 and 22:
Week 6 and 12: CNS Acute Pain Review (Telephone)
Appointment 23 -28:
Week 6 – 24: WH Physiotherapy
(3 Face to Face and 3 Telephone Reviews)
Appointment 29:
Week 16: Surgical Team Review (Face to face)
Appointment 30:
Week 24: Radiology VCMG , if required

MONTH 9

UCLH Chronic Pain Management
UCLH Psychology Management

CLINICAL DECISION MAKING MDT 2

POST CLINICAL DECISION MAKING MDT
Appointment 31: CNS Phone review

SURGERY 2: Mesh Removal +/-Continence/Prolapse Repair

Pre-SURGERY 2
Surgical Team Consent:
Appointment 32: F2F Consent
Appointment 33: Phone Consent Confirmation 4 weeks later
UCLH Pre-Assessment Anaesthetic Review
Appointment 34: F2F Review
Acute Pain CNS Review
Appointment 35: Phone Review

MONTH 12

POST-OP OPD FOLLOW UP
Appointment 36 and 37:
Week 1 (if catheterised) and 4 (non-catheterised): CNS Review (Telephone)
Appointment 38 and 39:
Week 6 and 12: CNS Acute Pain Review (Telephone)
Appointment 40, 41, 42:
Week 24: Final Review (Face to face): Physiotherapy, Psychology, Pain Medicine, Radiology (assessment for remnant mesh if patient chooses)

MONTH 18

LONG TERM FOLLOWUP PATHWAY
ANNUAL PATIENT REVIEWS
CNS REVIEW:
Appointment 43, 44, 45, 46, 47:
TELEPHONE 12M, 24M, 36M, 48M, 60M
PROMS 12M, 24M, 36M, 48M, 60M

-- Outpatient Visits
-- Surgery Pathway
-- MDT

Key:
F2F: Face to Face
VCMG: Video Urodynamics
: Letter to GP on UTI management, pain management, mesh passport update

Patient Walkthrough

SHP/SCP/RECTOPEXY MESH MDT PATHWAY

TRIAGE MDT

MONTH 0

POST TRIAGE MDT
Appointment 1: CNS Phone Review
Imaging: MR Pelvis +/- US Pelvis

OPD 1: Clinical Assessment (3 APPOINTMENTS)
Appointment 2: UG and COLO-RECTAL Team (F2F)
Appointment 3: Chronic Pain Team (F2F)
Appointment 4: Psychology (F2F)

SURGERY 1: Mapping Procedure

CLINICAL LCMC COLO-RECTAL MDT 1

MONTH 3

POST CLINICAL DECISION MAKING MDT
Appointment 5: CNS Phone review

UCLH Chronic Pain Management
UCLH Psychology Management

SURGERY 2:
Laparotomy

EDUCATIONAL ONLINE SCHOOLS

ONGOING CARE
Appointment 6, 7, 8, 9: CNS Key Worker Phone Review (Reviews every 8 weeks)
Appointment 12: Psychology F2F Reviews (every 12 weeks)

MONTH 9

Pre-SURGERY 1 - MAPPPING
Optimization of Patient
Stoma Nurse Review
UCLH Pre-Assessment Anaesthetic Review
Surgical Team Consent:
Appointment 15: F2F Consent
Appointment 16: Phone Consent Confirmation 4 weeks later
Appointment 17: F2F Review
Acute Pain CNS Review
Appointment 18: Phone Review

SURGERY 2 – DEFINITIVE PROCEDURE
48 hours PACU/HDU
Ward based 5-14 days
POST-OP OPD FOLLOW UP
Appointment 19 and 20:
Week 2 and 4: CNS Review (Telephone)
Appointment 21 and 22:
Week 6 and 12: CNS Acute Pain Review (Telephone)
Appointment 23 -28:
Week 6 – 24: WH Physiotherapy
Appointment 29:
Week 16: Surgical Team Review
Appointment 30:
Week 24: Radiology (if Stoma Reversal)

ONGOING CARE
Appointment 10,11: CNS Key Worker Phone Review (Reviews every 8 weeks)
Appointment 13, 14: Psychology F2F Reviews (every 12 weeks)

MONTH 12

CLINICAL LCMC COLO-RECTAL MDT 2

POST CLINICAL DECISION MAKING MDT
Appointment 31: CNS Phone review

UCLH Chronic Pain Management
UCLH Psychology Management

MONTH 18

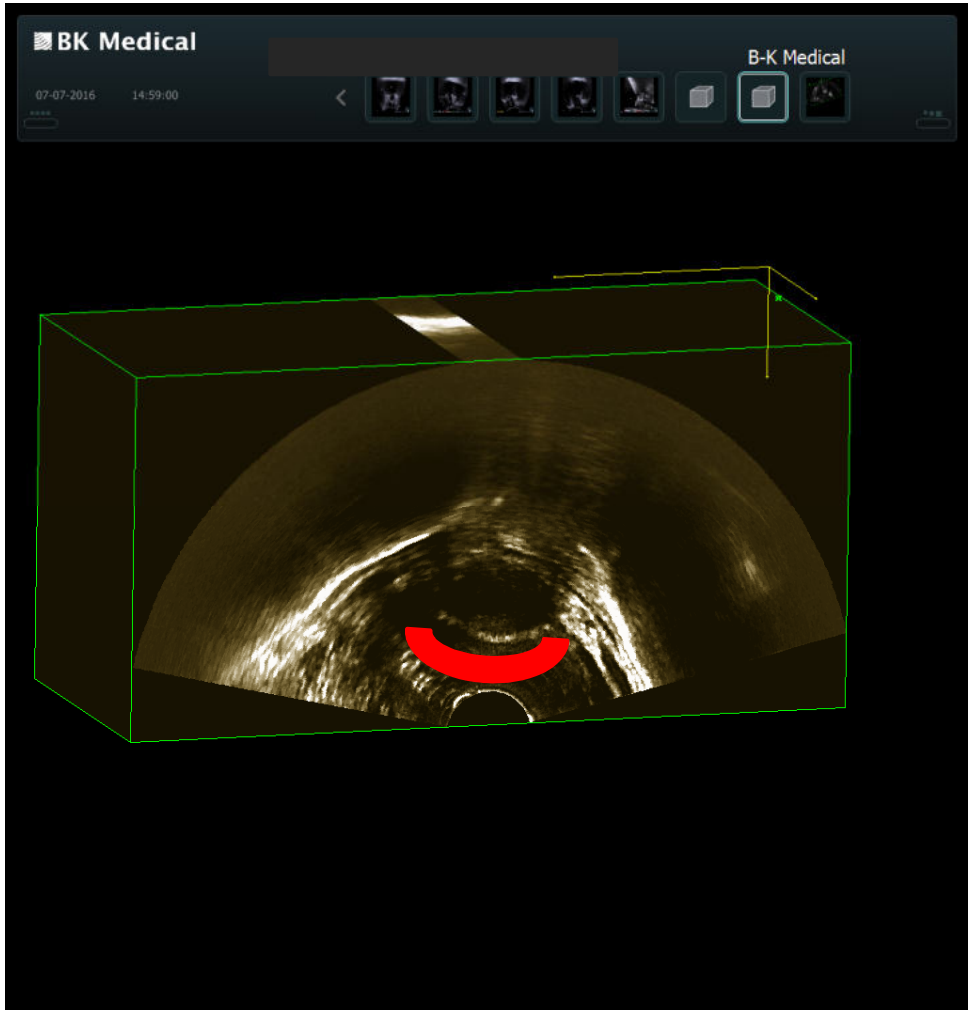
SURGERY 3: IF REQUIRED –
RECONSTRUCTIVE SURGERY
Recurrent Prolapse +/- Continence Repair

LONG TERM FOLLOWUP PATHWAY
ANNUAL PATIENT REVIEWS
CNS REVIEW:
Appointment 43, 44, 45, 46, 47:
TELEPHONE 12M, 24M, 36M, 48M, 60M
PROMS 12M, 24M, 36M, 48M, 60M

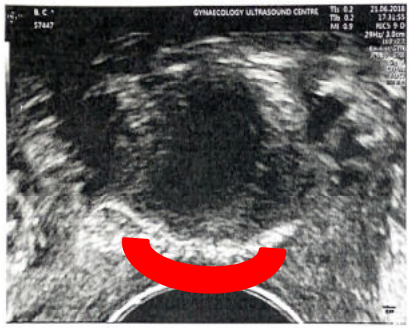
-- Outpatient Visits
-- Surgery Pathway
-- MDT
Key:
F2F: Face to Face
: Letter to GP on management

IMAGING

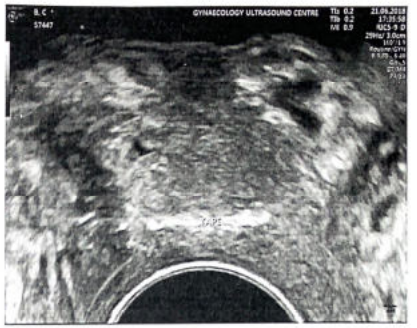
3-D USS



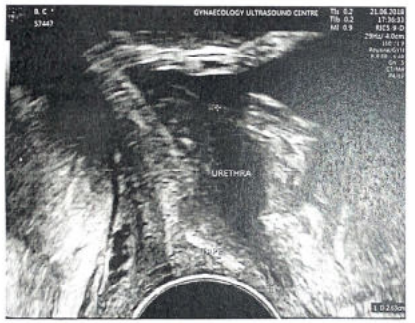
2-D USS



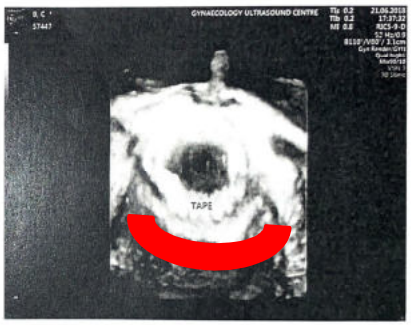
mesh tape in situ



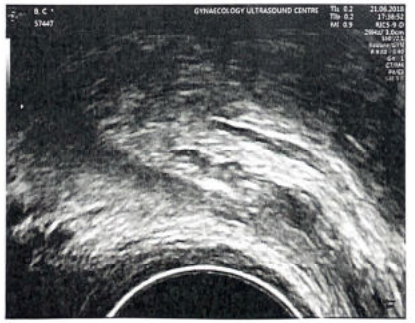
mesh tape in situ



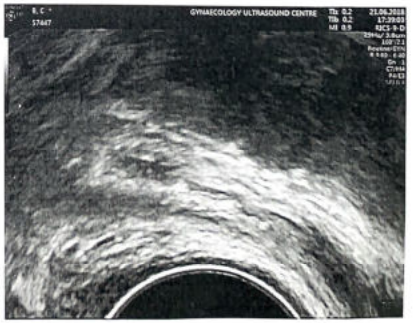
Urinary bladder, Urethra mesh tape in situ underneath the distal urethra



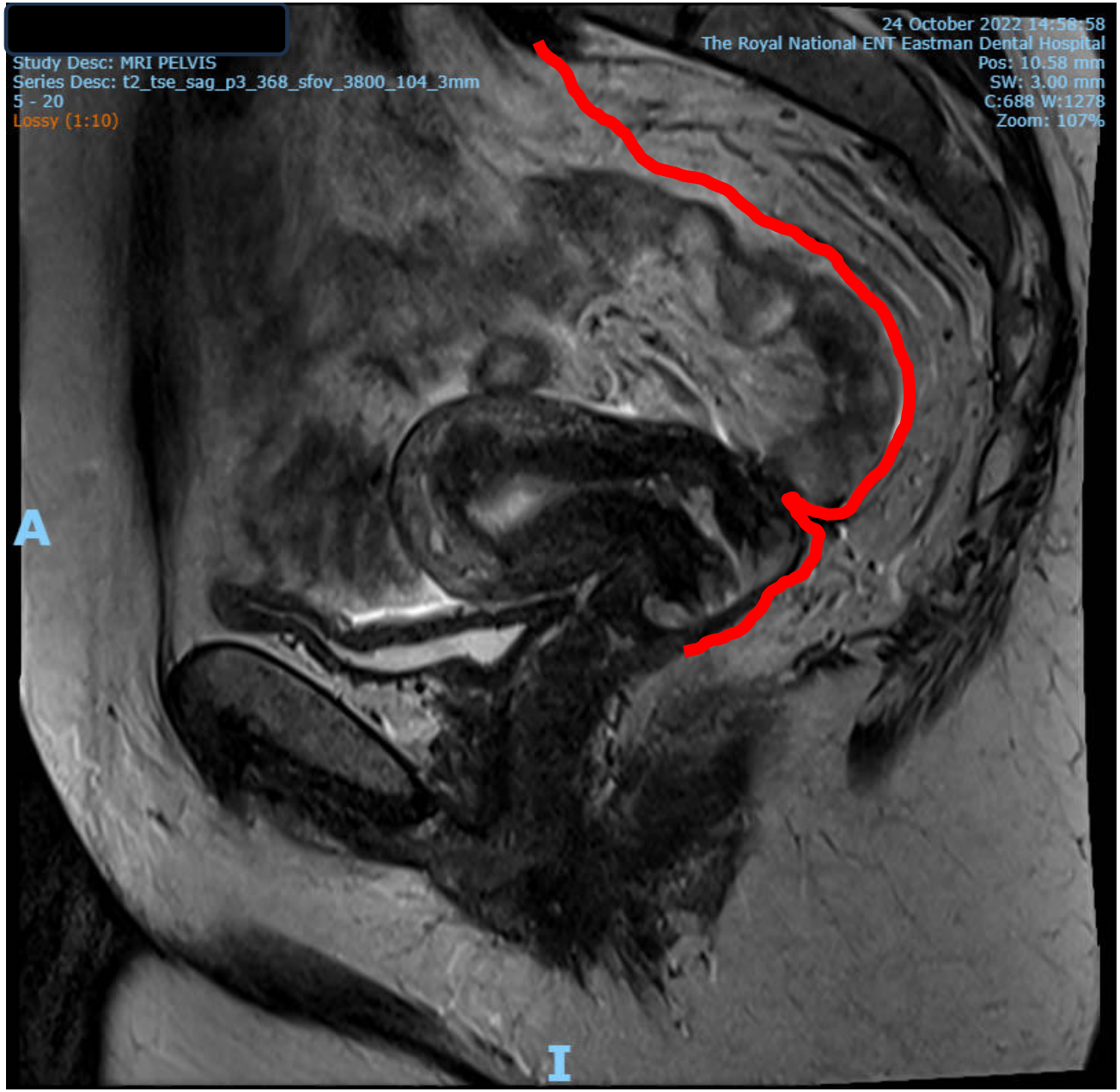
mesh tape in situ 3D



Right ureter



Left ureter



MR Pelvis Date: 24/10/22

Clinical Indications:
mesh protocol: recopexy mesh, rectal and lower abdominal pain

Findings:
The upper end of the mesh **sacrocolpopexy** is unfortunately not covered on the axial sequences. It is however visualised on the coronal and sagittal sequences and I feel these are sufficient to adequately assess her mesh in this case.

The mesh follows a normal course from its insertion anterior to L5-S1 through the right posterior pelvis to insert onto the operating in the approximate level of the rectosigmoid junction. A number of small bowel loops closely abuts the mid portion of the mesh and whilst there is no evidence of bowel perforation and there may well be adhesions at this site.

The rectosigmoid junction and posterior fornix of the vagina are closely opposed to the insertion point of the mesh rectopexy with both likely adherent to the mesh.

No other significant abnormality demonstrated.
No alternative cause for pain identified.

CONTINENCE MESHES

Stage 1 Mesh Removal

Stage 2 Mesh Removal

Long Term Rehabilitation and Follow Up

VAGINAL POP MESHES

Stage 1 Mesh Removal

Stage 2 Mesh Removal

Long Term Rehabilitation and Follow Up

ABDOMINAL POP MESHES

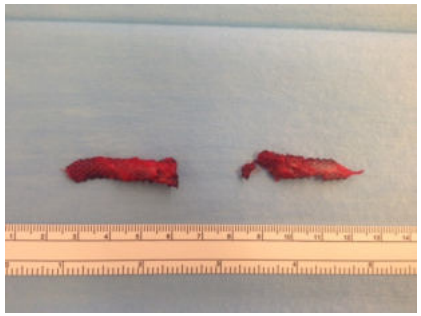
Mapping Procedure

Definitive Mesh Removal Procedure

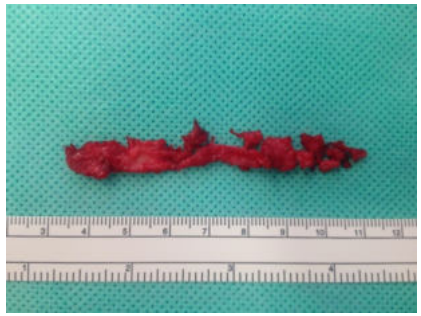
Reconstruction Procedure

Long Term Rehabilitation and Follow Up

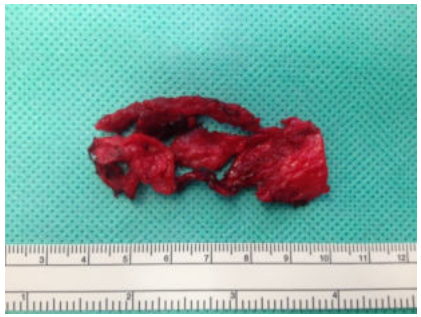
Removed Mesh



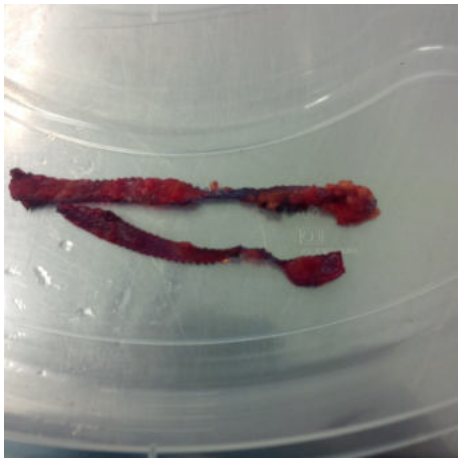
Removal of the arms of a TVT-O mesh that the central part had been removed elsewhere



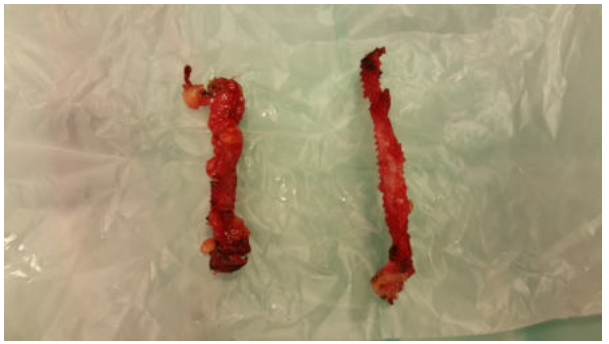
Removal of entire TVT-O mesh (piecemeal as impregnated into the urethra)



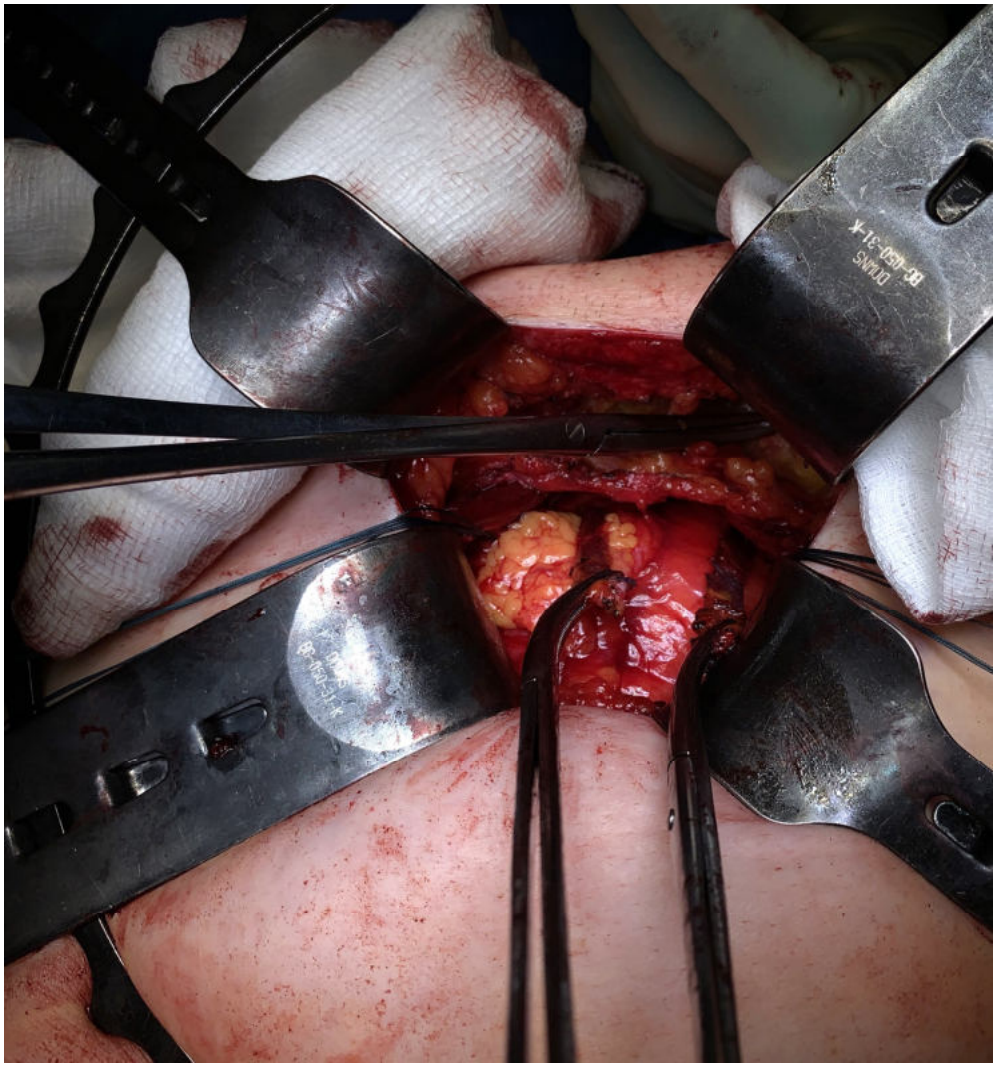
Removal of anterior vaginal wall mesh (piecemeal as impregnated into the bladder wall and urethra)

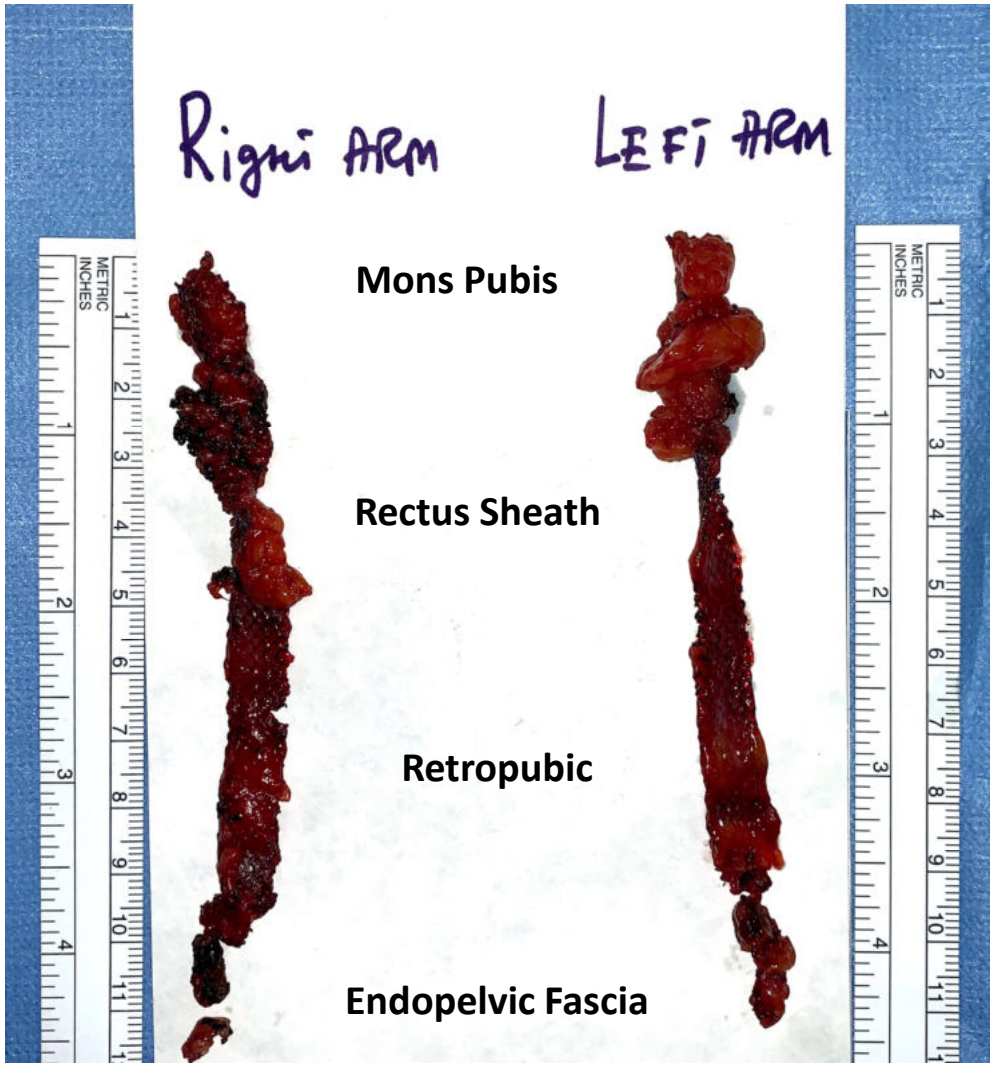


TVT Arms

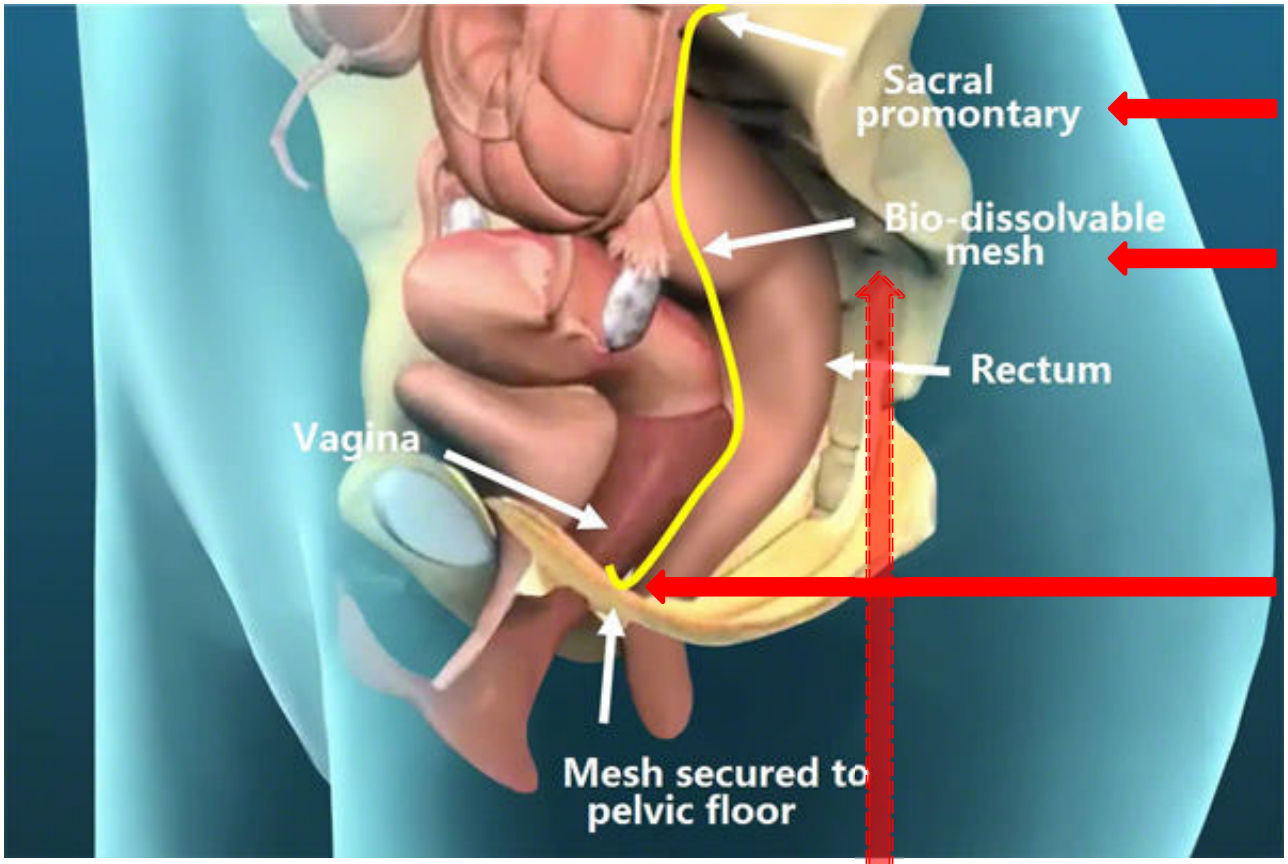


Use IUGA Mesh Complications Classification




Right ARM
LEFT ARM
Mons Pubis
Rectus Sheath
Retropubic
Endopelvic Fascia

Surgical Risks

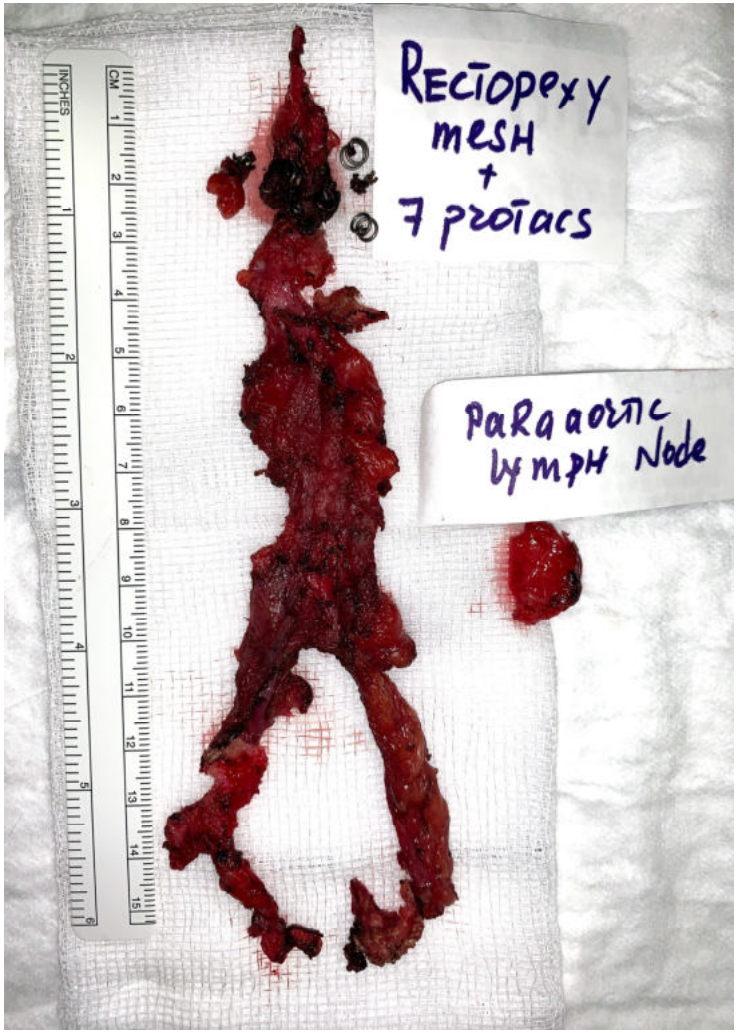


Vascular injury
Audit risk assessment (n=55) 1:7

Uterus +/- Cervix
Tubes +/- Ovaries
Vagina
Audit risk assessment (n=55) 1:2

Perineal body
Colo-anal anastomosis breakdown
Fistula
Audit risk assessment (n= 55) 1:8

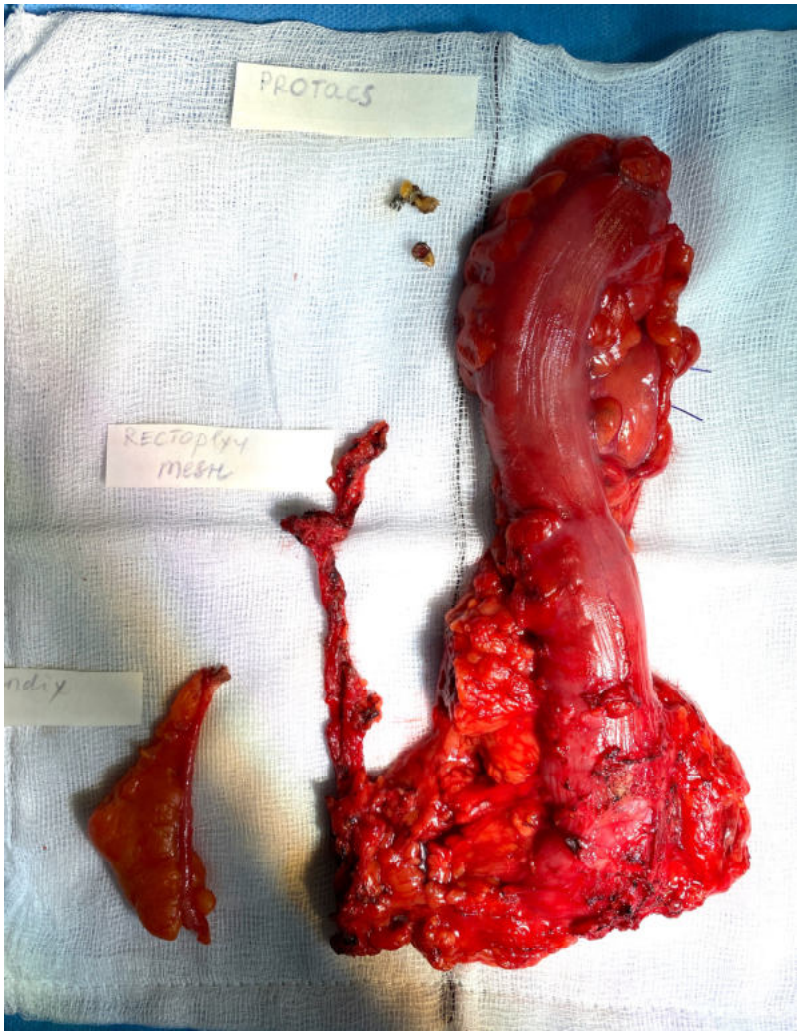
Nerve injury/Neuropathy
Audit risk assessment (n=55) 1:5



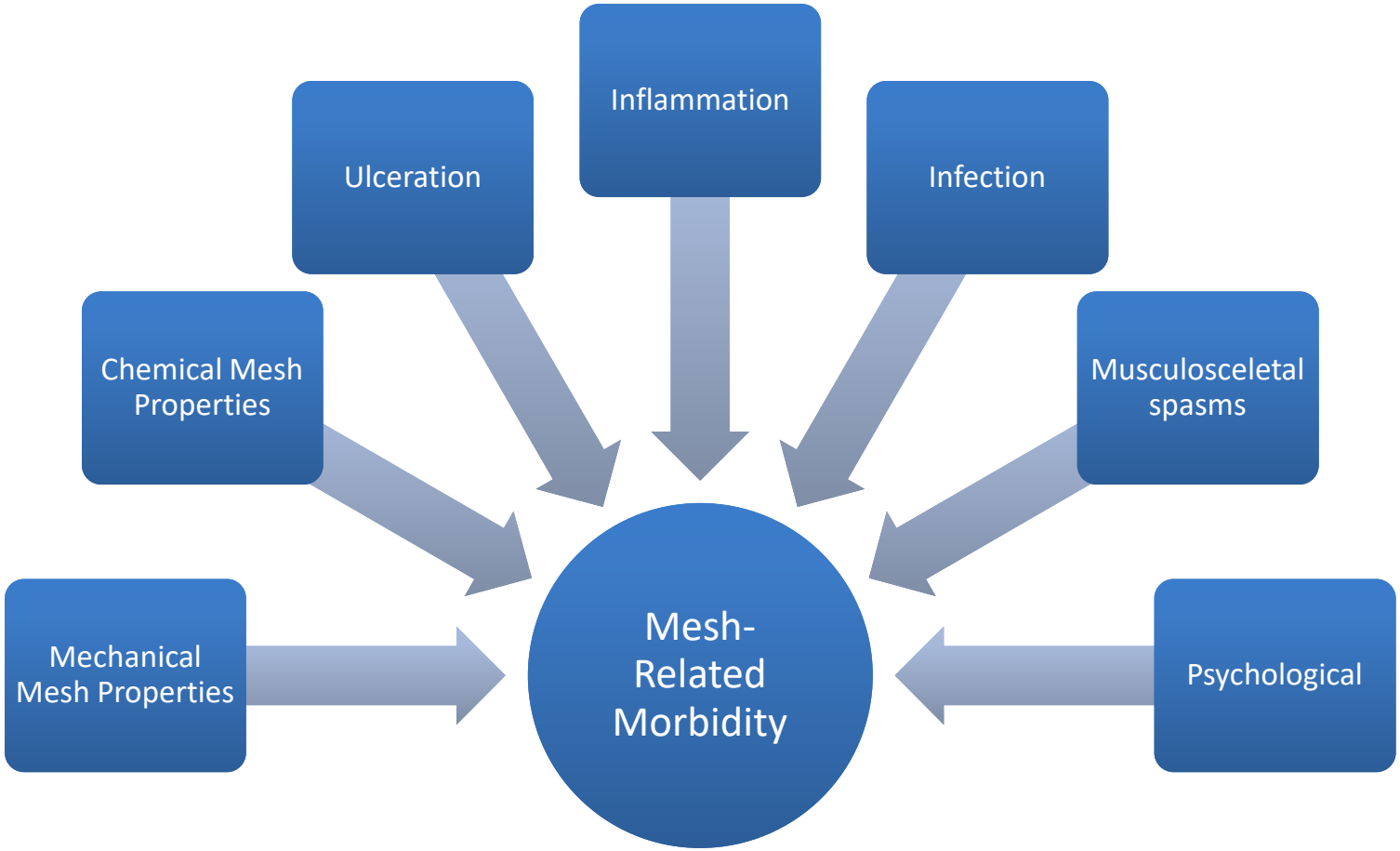
Sacral Promontory

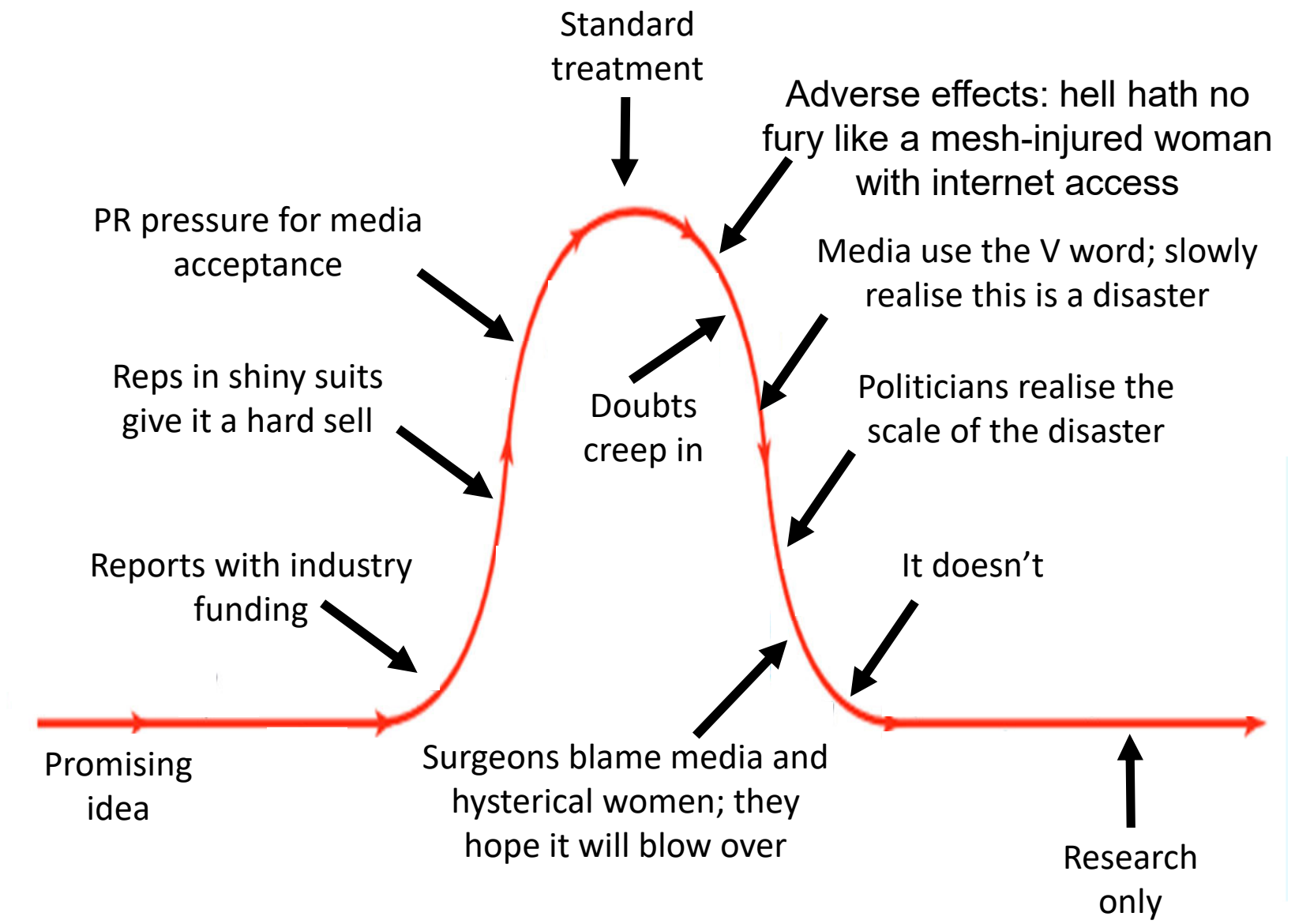
Rectal Application of Mesh

Perineal and Anal Sphincter Region



Multi-factorial Problem





Scott's parabola: adapted from BMJ VOLUME 323 22–29 DECEMBER 2001

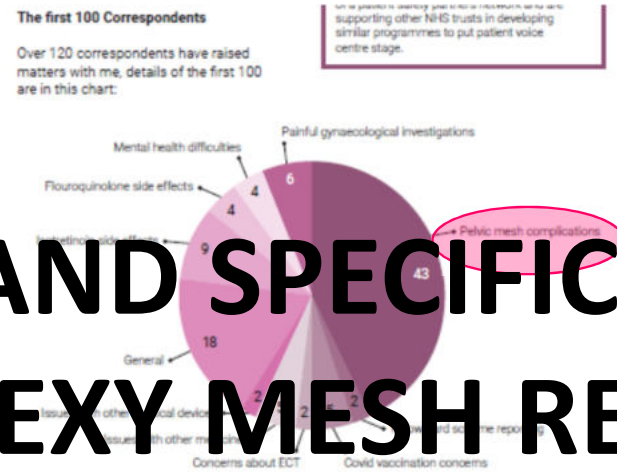
LCMC Governance Structure

CLINICAL GOVERNANCE

7 PILLARS OF CLINICAL GOVERNANCE TO BE FULFILLED:

1. **Clinical Effectiveness and Research**
    a. PROMS: Pre- and Post- interventions including outcomes of surgery/pain management/psychology/ nursing care and physiotherapy as reported
    b. Quality of service and Friends/Family Test
    c. Clinical and scientific research as part of FPMRS Group based at IfWH
2. **Audit**
    a. All aspects of pathway need to be audited including Timeliness, Fulfilment of Pathway Route, Patient Pathway Checklist completion, etc.
    b. Demographic and Geographic Reporting
    c. Clinical audit outcomes as defined in Pillar 1
3. **Risk Management**
    a. As outlined in the business case strategy
    b. Complaints management: Root Cause Analysis and SWOT Analysis reviews
    c. Medico-legal Claims: Website needs to clarify ‘evolutionary process of mesh complication management’

Patient Safety Commissioner Visit 20th Feb 2023



NHS ENGLAND SPECIFICATIONS OF RECTOPEXY MESH REMOVAL

What I will do

On pelvic mesh, to:

- co-produce resources for patients and GPs about side effects from pelvic mesh surgery
- [illegible] and to provide [illegible] mesh centres
- work with the health system to ensure that information is available to all patients on national registries

My top three priorities are

- Culture change
- Pelvic mesh complications
- Sodium valproate

UCLH only Centre in 2023

But are Complex Mesh Centres working?

Patient Safety Commissioner
Listening to Patients

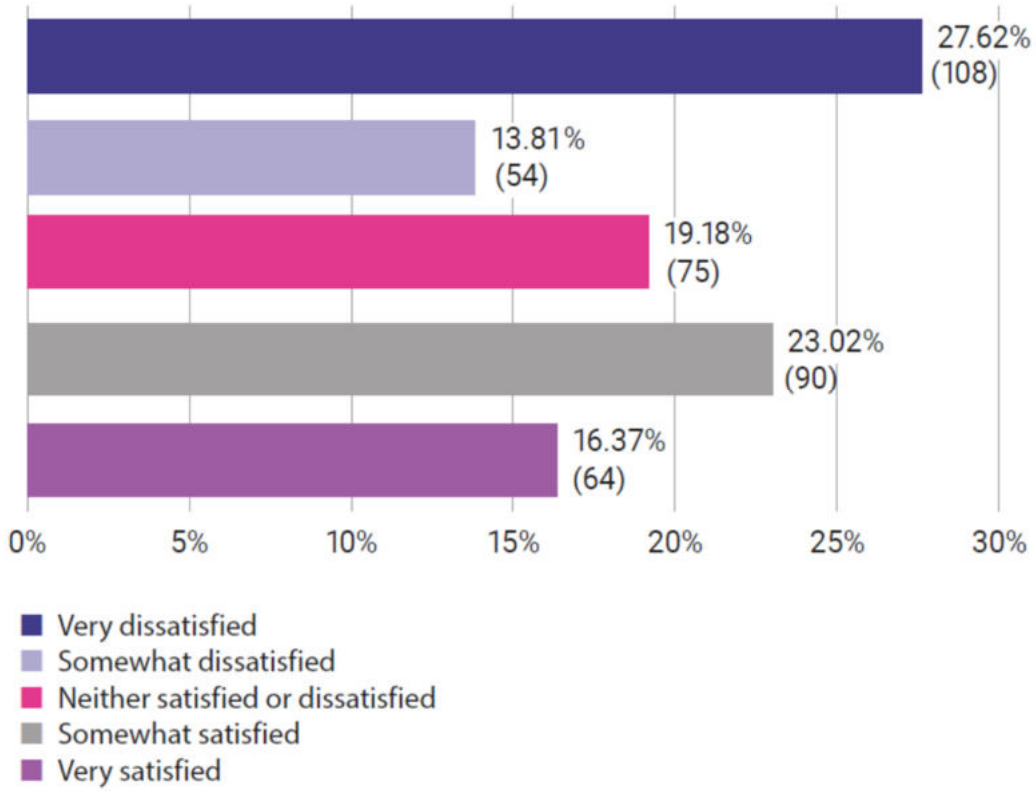
REDRESS

The Hughes Report

Options for redress for those harmed by valproate and pelvic mesh

07 February 2024

Figure 2: How satisfied are you with the NHS specialist mesh centres? ('N/A' respondents removed)



Source: Patient Safety Commissioner, Patient Engagement Survey[90]

MEDICO-LEGAL ISSUES

Implantation
- Consent
- Patient information leaflets: Industry led
- Training: Industry led
- Professional societies: minimally involved

Explantation
- Consent
- Patient information leaflets: patient and clinician led
- Training: not established (no gold standard)
- Centres: not determined
- Professional societies: mixed messages – advise being determined by none removal surgeons

Medical experts
- All implantation surgeons
- Advising patients to sue explantation surgeons
- Advising NHS England and Commissioning groups

Continence/Prolapse mesh inserted by:

- Gynaecologist with Specialist Interest Urogynaecology (RCOG registered)
- Female Urologist (RCS registered)
- Subspeciality Urogynaecologist (RCOG and GMC accredited)

Complications with mesh occur (average time 7 years)

Referral back to implanting surgeon – patients feel 'gaslighted'

Patients seek help from web-based patient advocacy groups such as *Sling The Mesh*

Patients advised to seek help from consultants with expertise in mesh complications:
Pre-July 2021:
3 surgeons *trusted* by patients
Post-July 2021:
7 National complex mesh centres created (I Lead for London)

Gaslighting Patients

Gaslighting CM Surgeons

MEDICO-LEGAL PATHWAY USED BY ME AND CURRENT *'NO-WIN NO-FEE'* FIRMS

Patient sues implanting surgeon

Medical expert (ME) selected by Law Firm is a mesh implanting surgeon

Legal team only asks for information on Breach of Duty and Causation of Mesh Implantation

- *Fact: ME is expert on implantation of mesh – NOT on explantation*
- *Fact: Mesh explantation surgical techniques only now been developed*
- *Fact: GMC credentialling for explantation being developed*
- *Fact: ME NOT appointed in one of 7 national Complex Mesh Centres*
- *Fact: ME potentially misdirecting the patient, court and legal firms*

Timeline of Mesh Crisis in UK (see attached document)

ME Outcomes (collated from several reports):
- Advises 'no harm done when mesh inserted, as mesh is 'gold standard'
- Advises patient is beyond the statute of limitations of 3 years
- Advises 'no case to answer' even though:
  - Mesh poorly/wrongly positioned
  - Mesh eroded into organ
  - Mesh was never required/indicated for patients initial condition
  - Substandard consent
  - Therapeutic options not discussed
  - Complications not discussed

ME Unsolicited non-expert advice (collated correspondence to patients:
- Advises harm done when mesh explanted
- Advises as explantation within 3 years of case – sue the explanting surgeon for damages instead
- If patient will not sue explanting surgeon, will advice legal firm to drop implanting case
- If patient will not sue explanting surgeon, will advice Legal firm to refer this surgeon to GMC instead (if Legal firm will not do so, ME will submit report directly– often without knowledge of the firm or patient)

UNDERSTANDING MEDICO-LEGAL SCENE IN CONTINENCE & PROLAPSE MESH

'SLAPP'

Acronym

Strategic lawsuits against public participation or *strategic litigation against public participation*

Definition in Law

Lawsuits intended to censor, intimidate, and silence critics by burdening them with the cost of a legal defense until they abandon their criticism or opposition.

What is SLAPP law UK?

'an alleged misuse of the legal system, and the bringing or threatening of proceedings (in medicine this often includes the GMC), in order to harass or intimidate another who could be criticising or holding them account for their actions and thereby discouraging scrutiny of matters in the public interest.'

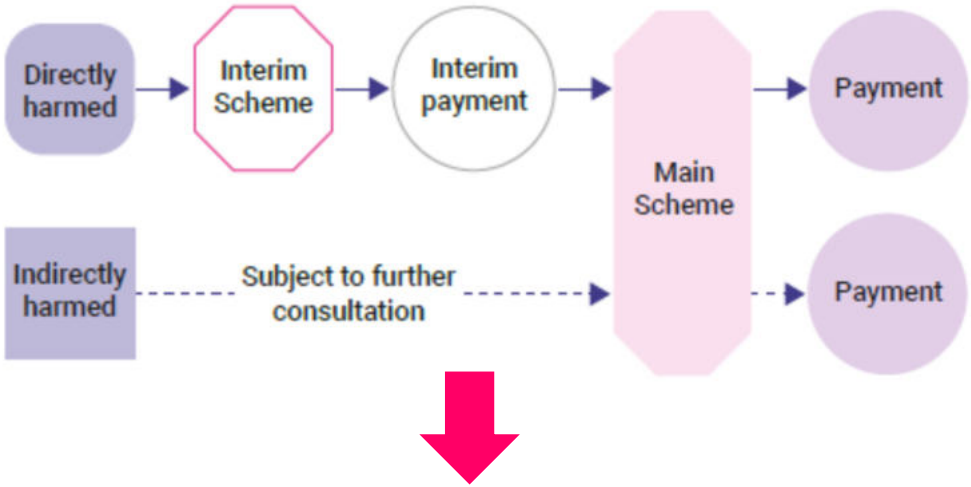
REDRESS

What would a redress scheme mean to patients?

- Security
- Apology
- Financial security
- Compensate for pain and trauma
- Access to social services
- Empathy
- Care plan
- Housing security
- Acknowledgement
- An explanation
- Recognition
- Pension security
- Heard
- Closure
- Take responsibility
- Improved quality of life
- Meaningful action
- Accountability
- Compensate for loss of earnings
- Support with additional living costs
- Security for the future
- Cover additional healthcare costs

Source: Patient Safety Commissioner, Patient Engagement Survey, thematic analysis of question 26

Infographic 2B: A two-stage process for redress: an Interim Scheme and a Main Scheme



Response stated to be about which intervention	Median quantum for an interim payment	Mean quantum for an interim payment
Pelvic mesh	£20,000	£139,556
Valproate	£100,000	£340,907
Combined pelvic mesh and valproate responses	£25,000	£167,553

Modern Hippocratic Oath 1964

I swear to fulfill, to the best of my ability and judgment, this covenant:

I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.

- I will apply, for the benefit of the sick, all measures which are required, **avoiding those twin traps of overtreatment and therapeutic nihilism.**
- I will remember that there is **art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.**
- **I will not be ashamed to say "I know not," nor will I fail to call in my colleagues when the skills of another are needed for a patient's recovery.**
- I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. **Above all, I must not play at God.**
- I will remember that **I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability.** My responsibility includes these related problems, if I am to care adequately for the sick.

Louis Lasagna, Dean of the School of Medicine, Tufts University

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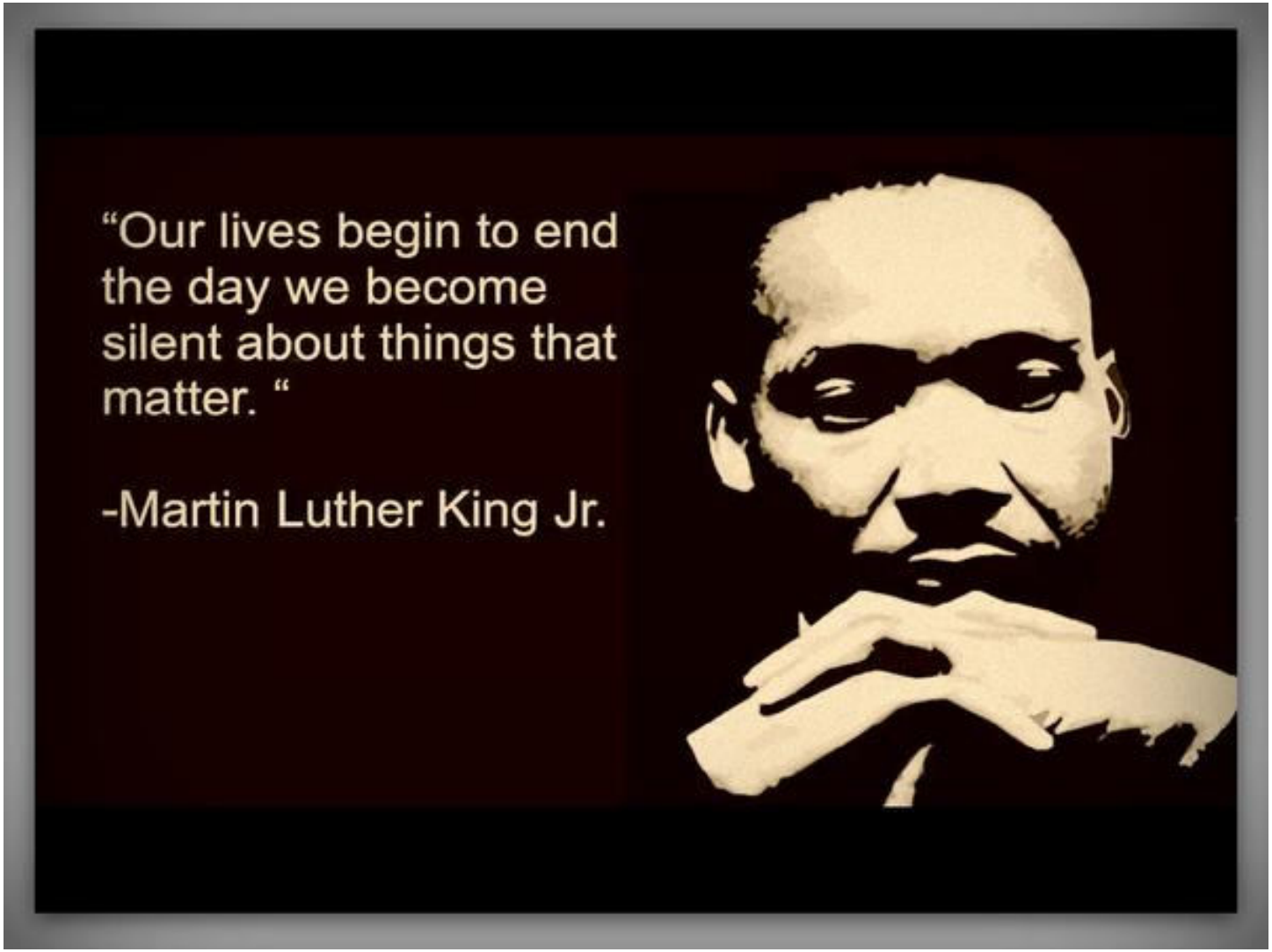
“Our lives begin to end the day we become silent about things that matter. “
-Martin Luther King Jr.

Thank-you

Original LCMC MDT, March 2022